Clinical Trial Training for the Research Teams

Hsu Tsui-Wen[1], Chih-Shung Wong [2]

[1]Institute Review Board Cathay General Hospital, Taipei, Taiwan.

[2]Department of Anesthesiology CGHIRB, Cathay General Hospital Taipei, Taiwan

國泰綜合醫院
Cathay General Hospital

國泰醫療財團法人

Background

- Well-trained clinical researchers can facilitate clinical trials while enhancing their research knowledge and ability to conduct trials.
- Adequate training is consistent with key clinical and regulatory objectives:
  - provide high-quality clinical trials
  - ensure that staff have the skills, competencies and capabilities requirement and appropriate qualification.

Background

In 2024 revised version of the Declaration of Helsinki.

- Article 12 states: Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications.
- Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

Aims and Methods

AIMS

- To achieve the goals of the GCP training standards, TFDA has provided supplemental funding to support the project: Strengthening the Training and Qualifications of Clinical Research Professionals (MOHW112-FDA-D-113-000452).
- The goal
  - Improve the scientific quality and ethical knowledge of clinical trials through enhanced training for all investigators.

Materials and Methods

The training program was designed with two primary components:

- **The first** is training of clinical research professionals in clinical trials on the basics of GCP.
- **The second** aim is training on advanced knowledge and the latest clinical trial trends.
- Trainees included representatives from the pharmaceutical industry, clinical trialists, and the Taiwan Drug Administration (TFDA); as well as participating clinical research professional associations, collaborative institutional training programs, and institutional review board members.

Methods

- Survey question design uses pre-designed self-administered questionnaires
- Course effectiveness evaluation, using the lecturer’s test questions as positive scores for pre- and post-tests
- This study conducted 4 basic education training sessions and 1 advanced training course.

Results

Results

- A total of 564 participants of the course, and the final number of participants was 435; the attendance rate was 77.1% and total 430 people were included for the analysis.
- Among basic education participants, 63.8% were female, 42.3% were over the age of 45, the majority of participants were from hospitals (57.9%) and 43.3% had submitted research protocol for review in the past five years, as shown in Table 1.

Table 1. Demographic characteristics of survey respondents (n=430)

variables	n(%)
gender	
male	160(37.2%)
Female	**270(63.8%)**
age	
Under 25 years old	28(6.5%)
26-30	38(8.8%)
31-35	49(11.4%)
36-40	66(15.3%)
41-45	67(15.6%)
Over 45 years old	**182(42.3%)**

Variables	n(%)
service unit	
In Hospital	**249(57.9%)**
CRO	4(0.9%)
Academia	86(20%)
Biotechnology company	34(7.9%)
IRB staffs	11(2.6%)
IRB members	20(4.7%)
Other	26(6%)

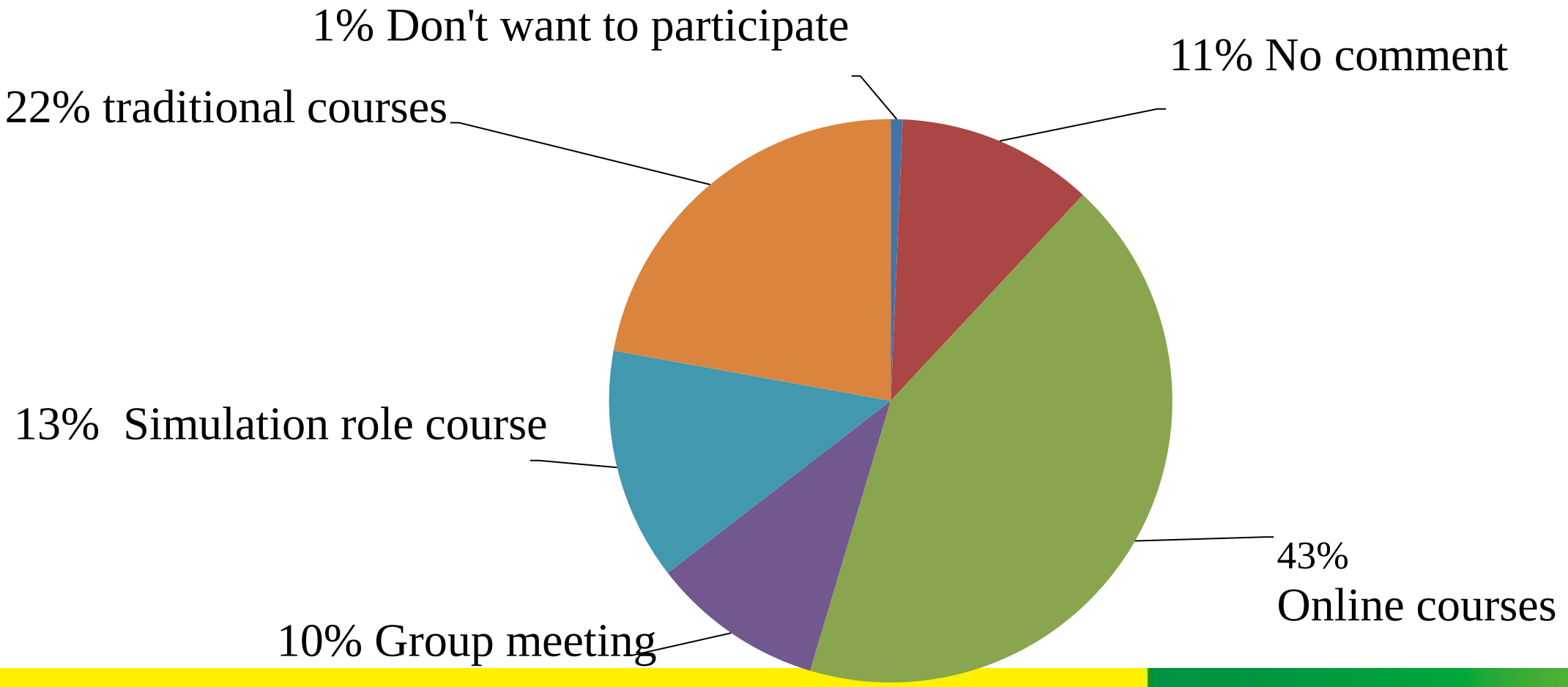
Table 2 . Analysis of gender differences in learning effects

	pretest score	Post score	P value
	mean±sd	mean±sd	
Gender			
Male	67±5.8	87.2±2.9	<0.001
Female	66.9±6.2	87.6±1.7	<0.001
Total	67.0±8.8	87.5±5.6	<0.001

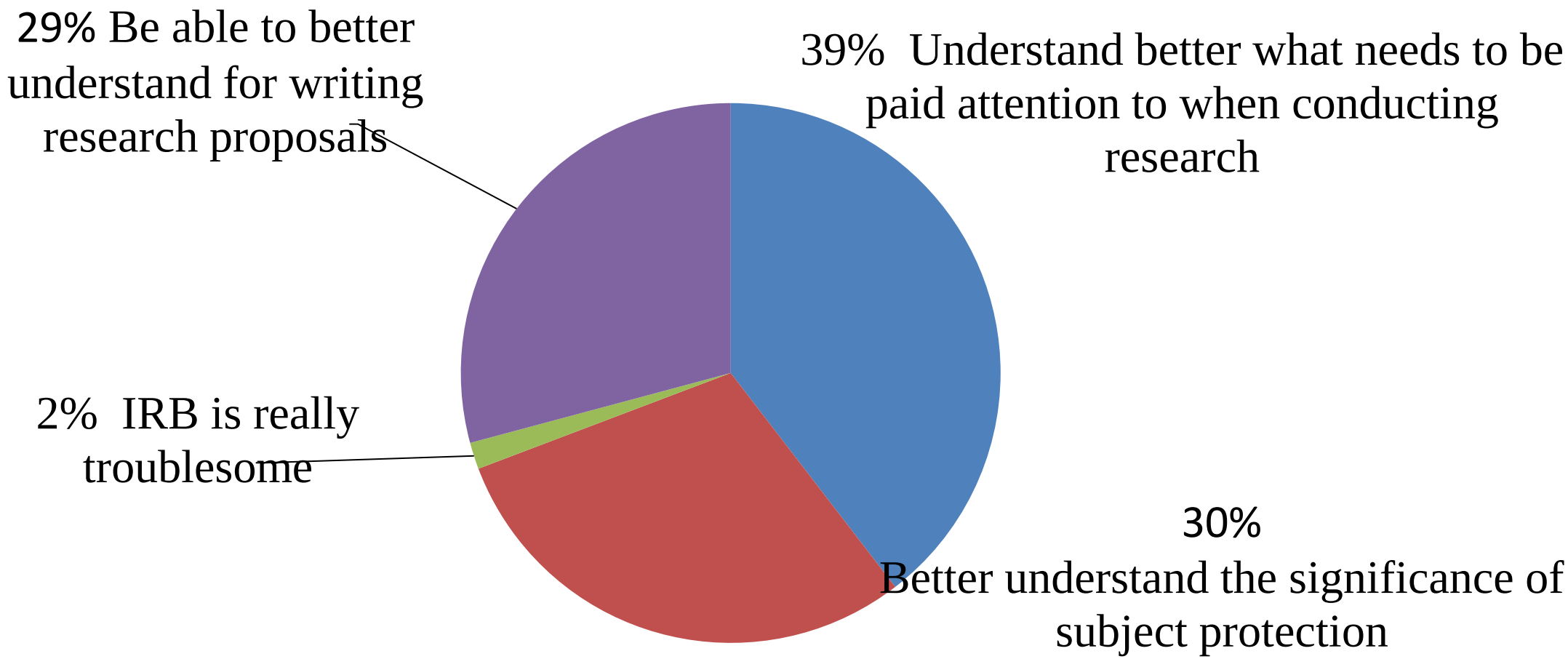
Results

- Before and after the course, there was a significant difference between gender and learning outcomes ($p<0.001$), as shown in Table 2.

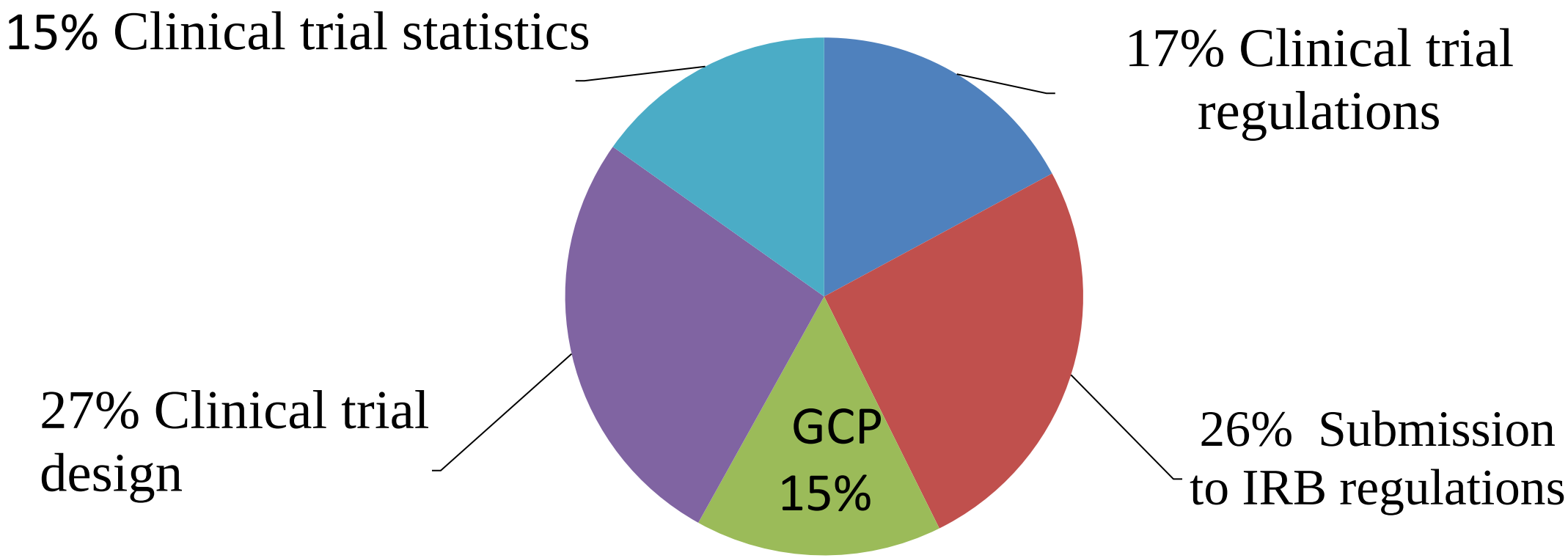
Courses you are interested in taking



Did you gain anything from this seminar?



Courses you were interested in participating in in the future



Conclusion

- Future course design will focus on four key areas: authorities, project sponsors, industry and IRBs.
- By integrating the responsibilities and obligations of all parties, we adapt our curriculum to the changing research environment and improve the effectiveness and ethical standards of clinical trials.

Strengthening the Training and Qualifications of Clinical Research Professionals (MOHW112-FDA-D-113-000452)

- 98-person basic education training
- 125-person advanced seminar
- 99-person an international conference

- 72-person basic education training

- 70-person basic education training

- 70-person basic education training

Photos

Thank you for your attention.