GUIDELINES FOR TRAINING PROGRAMMING AND EVALUATION PRINCIPLES ON GETAT CLINICAL TRIALS AND GOOD CLINICAL PRACTICES

GUIDELINES FOR TRAINING PROGRAMMING AND EVALUATION PRINCIPLES ON GETAT CLINICAL TRIALS

1. AIM

These guidelines have been prepared to provide guidance on the form and content of the application to the General Directorate of Health Services regarding training programs planned to be organized on GETAT (Traditional and Complementary Medicine) good clinical practices and GETAT clinical trials.

2. BASIC PRINCIPLES

2.1. The number of people attending the training is limited to minimum 20 and maximum 80 people. However, this limitation does not apply when planning distance learning.

2.2. At least two workshops in accordance with the quality of the training are held. However, in distance learning, at least two videos are presented instead of workshops.

2.3. If it is in accordance with the planned training program, there is at least one role-play video presentation.

2.4. Laptop(s) with internet connection; projection system and sound system (including lapel microphone) should be available at the place of training.

2.5. At least one "questions-answers activity", preferably supported by computer software, is carried out.

2.6. It is preferable for the physical space where the training will take place to be a large hall prepared according to the table seating arrangement and to be able to be transformed into two small halls when necessary.

2.7. Throughout the course, there should be a course coordinator who can answer any administrative and training-related questions of the participants.

3. IMPLEMENTATION

3.1. Throughout the training, a quality assurance officer who has a good command of the subject should evaluate the presentation of the trainer, his/her capacity to answer the questions asked, and his/her interest in the trainees.

3.2. At the beginning of the training, the expectations of the participants should be questioned.

3.3. At the beginning of the training, a preliminary test of at least 10 (ten) questions should be conducted to measure the level of knowledge of the participants.

3.4. The trainings consist of four sessions, two in the morning and two in the afternoon. A roll call is made for each session. Those who were present during at least 3/4 of the roll calls are entitled to attend the exam held at the end of the training.

3.5. Each participant should be given a name badge, schedule, course handouts, as well as a notepad and a pen.

3.6. For trainings lasting more than a day, the training from the first day should be summarized in the beginning of the second day.

3.7. Before starting the advanced trainings organized after the basic training, a reminder should be made regarding the information provided in the basic training and only those who are successful in the basic training should be included in the advanced training program.

3.8. Presentations in the training should not exceed 45 (forty-five) minutes and workshops should not exceed 3 (three) hours.

3.9 It is preferable for the trainers involved in the training to participate throughout the training.

4. EVALUATION

4.1. Evaluations should be carried out under two titles: “evaluation of success” of the participants and “evaluation of the training program”.

4.1.1 Evaluation of the success of the participants: The success of the participants should be evaluated with an exam with a minimum of 10 (ten) questions, which is to be conducted at the end of the training, and those who are eligible to continue and found successful should be given a “certificate of achievement” and those who fail the exam should be given a “certificate of participation”. The passing grade in order to be given a certificate of achievement is at least 70 (seventy) over 100 (hundred).

4.1.2 Evaluation of the program: Participants’ feedback should be received to evaluate the effectiveness of the training program.

4.2. The course coordinator must have a signature on the “certificate of achievement” or “certificate of participation”.

4.3. These trainings should be repeated at appropriate intervals and, if requested by the General Directorate of Health Services, the certificate of achievement received at the end of the training should be renewed.

5. TRAINERS

5.1. Depending on the nature of the topics, the trainers should have received a training on the current (approved by the General Directorate of Health Services) GETAT clinical trials and GETAT good clinical practices, and they should be selected from experts.

5.2. Trainers other than faculty members must have received "training of trainers" and document this.

6. REQUIREMENTS FOR DISTANCE LEARNING PROGRAM

6.1. All aspects that are mentioned in this manual and are applicable also apply to the distance learning program. In addition, at least the following issues should be fulfilled:

6.1.1. Distance learning programs can be delivered by the Ministry of Health and its affiliated Institutions, Universities, Training and Research Hospitals, Relevant Associations and Foundations which are directly related to the subject, through the websites that will be created specifically for the training.

6.1.2. The basic structure of the training should be structured as: training programs, training modules, assessment questions, feedback. Each module should be composed of written, audio and visual elements that address a topic.

6.1.3. On the training site, there should not be any text or announcement which are not related to the subject and contain advertisement, other than the logo and name of the institution or private organization.

6.1.4. The institution that will carry out the training, the topics of the training, and the trainers providing the training should be clearly stated on the site where the training will be held.

6.1.5. It should be clearly stated on the main page that the program is approved by the General Directorate of Health Services. Training programs without the approval of the General Directorate of Health Services cannot be carried out and documented.

6.1.6. All users who will use the system must be registered. For this, a registration form must be filled. Information to be obtained in the registration form (name, surname, Turkish identity number, e-mail address, city, country, profession, field of expertise, time worked in the field of expertise, institution, duty, institution address, telephone, mobile phone) should also question the eligibility of the user for logging into this system. The user must confirm the accuracy of the information provided. After entering the user information, s/he should read the rules indicating his intended use and confirm that s/he has read and understood.

6.1.7. The confirmation e-mail containing the temporary account information should be sent to the user whose registration is approved. The user should enter the account information sent to him/her to the system and be asked to update his/her password for security reasons.

6.1.8. In accordance with the order of the training modules that constitutes the certification program, the prerequisites for each module should be as follows:

6.1.8.1. It is not possible to start a succeeding module without passing the preceding module.

6.1.8.2. At the end of each module, a grade is calculated according to the evaluation of the answers to the questions asked in that module; the passing grade cannot be below 70 (seventy).

6.1.8.3. The user receives the modules and tests in accordance with the determined certification program.

6.1.8.4. If the user, who started the training module in the certification program, leaves the system before completing the module, he can continue from where he left off for the relevant training when he re-enters the system.

6.1.8.5. The user lists the training modules completed, started and not yet started, from the training modules included in the certification program. S/he sees how much time s/he has spent in each module, how long it has taken for him/her to complete each module, and the completion date. For modules s/he has started but not completed, s/he sees how much s/he has completed as a percentage.

6.1.8.6. At the end of the modules, the user sees his/her status in the exams, monitors his/her answers to questions and his/her success.

6.1.8.7. Each program must be completed within a maximum of 6 (six) months, and each module within a maximum of 1 (one) month. In cases where this cannot be achieved, 12 (twelve) months must pass before the program can be reapplied.

6.1.8.8. The user answers end-of-module questionnaire and presents her/his opinions, if any, for each module. Opinions given for the module are approved by the module trainer or the site manager, responded if necessary, and then allowed to be seen by other users.

6.1.8.9. The completed module may be graded by the user.

6.1.8.10. The user can follow up the module and is informed when other users express their opinions with regard to the module.

6.1.8.11. The user who completes the certification program in accordance with the specified criteria is informed by the system that s/he has successfully completed the program. This information is transmitted by e-mail. Upon completion of the certification program, the user is given a certificate which is approved by the General Directorate of Health Services and is ready to be printed or downloaded.

6.1.9. The aim and the projected targets of each module are determined and written at the beginning of each module.

6.1.10. The time period spent for the module by each participant and all participants each year, the response success rate in each module, the total success rate, the module feedback grades and evaluations are evaluated by a "Quality Assurance Officer" throughout the training.

6.1.11. All activities of the user on the e-learning system are recorded.

6.1.12. Each login date and all activities carried out after each login are recorded and reported by the system as of sign up date.

6.1.13. The status of the user in each training module included in the certification program is reported. Starting date, completion date, the total time spent for the module, and the points obtained from end-of-module test are reported.

6.1.14. The users who have started, completed and continued each module as well as those users who have completed the certification program are listed.

7. APPLICATION AND PERMISSION

7.1. In accordance with official letter and the application form published on the website of the General Directorate of Health Services, an application should be lodged to the General Directorate at least one month ahead of start date of the training program. A regulatory approval is given to those deemed appropriate as a result of the evaluation.

7.2. The training should not be carried out without permission of the General Directorate.

7.3. The content of the presentations made during the application and during the training should be in accordance with the applicable legislation in our country.

7.4. Applications for distance learning programs are made in two stages:

7**.4.1.** The first stage is the stage of preliminary eligibility for certification. At this stage; program content, program providers, and program provision method should be clearly stated. The application should include standard working methods related to the distance learning process, and the quality control systems and the implementation stages should be clearly indicated. If at this stage the General Directorate decided it is eligible for certification, the program content should be placed on a demo web page but not made available.

7.4.2. In the second application to the institution, an opinion should be received by notifying the final version of the program and the demo web page address as well as the login password to these pages. If a positive opinion is received at this stage, the program can be brought into use and a certificate approved or given by the General Directorate as well as the program certification can be given to successful candidates with passwords and in a protected format.

8. ADMINISTRATIVE SANCTION

8.1. The applicant and the relevant persons are cautioned by the General Directorate if the training is organized or attended in violation of these Guidelines and the applicable legislation. If the said procedure continues following this caution, the applicant may not organize trainings for 6 (six) months.

9. ENTRY INTO FORCE

These Guidelines enter into force on the date of approval.

10. EXAMPLES OF TRAINING PROGRAMS

The following training programs are given as examples. The course content may change in accordance with the course title.

10.1. Basic course program on ethical approach in clinical trials

10.1.1. Training Duration: It should be minimum 1 day, maximum 4 days.

10.1.2. Target Audience: This training is aimed at members of the ethics committee and the investigators.

10.1.3. Aim: To understand primary ethical approaches and principles in clinical trials.

10.1.4. Two separate modules can be prepared:

Module 1: The scope of the training may include the following subjects:

- The philosophy and historical development of ethical approach in clinical trials
- The ethical dimension of clinical trials
- The national legislation in clinical trials
- Tasks, authorities and responsibilities of the ethics committee
- Trial ethics committees and their characteristics
- Establishment, functions and practices of the ethics committee
- Aspects which render a clinical trial ethical
- Misconduct in clinical trials
- Conflict of interest in clinical trials
- Statistical evaluation in clinical trials and reliability of trial results
- Ethical approval process
- The ethics committee/investigator/sponsor/contract research organization relations

Module 2: The scope of the training may include the following subjects:

- Quality control and assurance in clinical trials
- The methodology in clinical trials
- Statistical approaches in clinical trials
- Safety notifications and evaluation in clinical trials
- Clinical trials on children
- Clinical trials on the elderly
- Clinical trials and the use of placebo in psychiatry
- The ethical dimension of genetic trials
- Ethical approaches related to female volunteers in clinical trials
- Clinical trials on healthy volunteers
- Sources of error in different types of trials
- Ethical dimension of observational studies
- Problems encountered in implementation

11.3. Introduction to/basic training on clinical trials

11.3.1. Training Duration: It should be minimum 1 day, maximum 4 days.

11.3.2. Target Audience: This training should aim at the investigators and sponsors.

11.3.3. Aim: To understand fundamental principles in clinical trials.

11.3.4. Two separate modules can be prepared:

Module 1: The scope of the training may include the following subjects:

- Fundamental principles of GETAT Good Clinical Practices
- The significance of Declaration of Helsinki and the points to be followed
- The process of developing a new GETAT product
- Terminology in GETAT clinical trials
- Observational studies

- Tasks and responsibilities of the parties in clinical trials
- Information of volunteers and the informed consent form
- Legislative regulations
- Safety notifications
- Practices carried out by the local authority as per the applicable legislation

Module 2: The scope of the training may include the following subjects:

- Clinical trial protocol
- Investigator's brochure
- Basic statistical concepts
- Concept of pharmacokinetics,
- Quality control in clinical trials
- Protection of the volunteer/patient and the Declaration of Helsinki
- Clinical trial design
- The methodology in clinical trials
- Placebo control in clinical trials
- The project management in clinical trials
- Special parameters in clinical trials (quality of life, etc.)
- Data management (data collection, data input, data validation, etc.)
- Data reliability/safety

12.4. Monitorization in clinical trials

12.4.1. Training Duration: It should be minimum 1 day, maximum 3 days.

12.4.2. Target Audience: This training should aim at sponsors and monitors.

12.4.3. Aim: To understand fundamental principles on monitorization in clinical trials.

12.4.4. Scope: The scope of the training may include the following subjects:

- Monitorization policy
- Legislative regulations in clinical trials
- GETAT Good Clinical Practices (GCP)
- Good laboratory practices (GLP)
- Quality assurance and standard operation methods
- Terminology in GETAT clinical trials
- Basic documents of trial file
- Inappropriate behaviors in clinical trials
- Selection and characteristics of the monitor
- The responsibilities of the monitor
- Reporting
- Data management (data collection, data input, data validation, etc.)
- Data reliability
- Counting, and disposal of investigational products