



AN APPROACH TO MEDICAL AND CLINICAL PHARMACOLOGY CLINICAL RESEARCH PRACTICES AT CAPA CAMPUS: A GOOD CLINICAL PRACTICES (GCP) TRAINING MODEL

Dr. Meral Demir, MSc, PhD

Title:

An approach to medical and clinical pharmacology clinical research practices at Capa Campus: A Good Clinical Practices (GCP) training model

Author(s):

Demir M^{1*}, Dizdar Y², Bebek N³, Akkaya V⁴, Tukek T⁴, Gürol AO^{1,5}, and Saip P^{6,7}

Affiliation(s):

¹MSc., PhD, Department of Medical Pharmacology and Clinical Pharmacology, Istanbul Faculty of Medicine, Istanbul University, Fatih, Capa 34093, Istanbul, Turkey

²MD, PhD, Assistant Professor, Department of Radiation Oncology, Institute of Oncology, Istanbul University, Fatih, Capa 34093, Istanbul, Turkey

³MD, PhD, Professor, Department of Neurology, Istanbul Faculty of Medicine, Istanbul University, Fatih, Capa 34093, Istanbul, Turkey

⁴MD, Professor, Department of Internal Medicine and Emergency Internal Medicine, Istanbul Faculty of Medicine, Istanbul University, Fatih, Capa 34093, Istanbul, Turkey

⁵MD, PhD, Professor, Department of Immunology, Aziz Sancar Institute of Experimental Medicine, Istanbul University, Fatih, Capa 34093, Istanbul, Turkey

⁶MD, Professor, Department of Clinical Oncology and Medical Oncology, Institute of Oncology, Istanbul University, Fatih, Capa 34093, Istanbul, Turkey

⁷MD, Professor, Department of Internal Medicine and Medical Oncology, Istanbul Faculty of Medicine, Istanbul University, Fatih, Capa 34093, Istanbul, Turkey

Subjects: Medical Sciences

Received: 04 December, 2019 | **Accepted:** 20 December, 2019 | **Published:** 23 December, 2019

***Corresponding author:** Dr. Meral Demir, MSc, PhD, Department of Medical Pharmacology and Clinical Pharmacology, Istanbul Faculty of Medicine, Istanbul University, Millet Street, Fatih, Capa 34093, Istanbul, Turkey, Tel: +902124142000-32414, +9005307343088; Fax: +902124142052; E-mail: meral.demir@istanbul.edu.tr, meraleecn13@gmail.com

ISBN: 978-81-943057-5-0 | **ISBN Date:** 7.7.2020

DOI: <https://dx.doi.org/10.17352/ebook10116>

ORCID: <https://orcid.org/0000-0002-6994-4275>

Citation: Demir M, Dizdar Y, Bebek N, Akkaya V, Tükek T, et al. (2019) An approach to medical and clinical pharmacology clinical research practices at Capa Campus: A Good Clinical Practices (GCP) training model. Peertechz Publications, ISBN: 978-81-943057-5-0

Table of Contents

004	➤ 1. Abstract
005	➤ 2. Abbreviations
006-009	➤ 3. Background <ul style="list-style-type: none">i. <i>The addition of a new lesson to the curriculum</i>ii. <i>Content of the practices</i>iii. <i>Creating resources for practice</i>iv. <i>Developing a practices evaluation model</i>v. <i>Targets and evaluation</i>
010-021	➤ 4. Materials and Methods <ul style="list-style-type: none">vi. <i>Content of lesson and resources</i>vii. <i>First-semester education</i>viii. <i>Formal structure of the measurement and evaluation form of first-semester education</i>ix. <i>Second-semester education</i>x. <i>Formal structure of the measurement and evaluation form of second-term education</i>xi. <i>Statistical analyses</i>
022-023	➤ 5. Results <ul style="list-style-type: none">xii. <i>Questionnaire Result</i>xiii. <i>Incoming suggestions</i>
024-027	➤ 6. Discussion <ul style="list-style-type: none">xiv. <i>Determination and evaluation of the subjects of the practices</i>xv. <i>Lesson load and satisfaction</i>xvi. <i>Educational model and evaluation of group schoolwork</i>xvii. <i>Gains and future goals</i>
028	➤ 7. Conclusion <ul style="list-style-type: none">xviii. <i>Ethics approval and consent to participate</i>xix. <i>Availability of data and materials</i>xx. <i>Author's contributions</i>
029	➤ 8. Acknowledgements
030-031	➤ 9. References

1

ABSTRACT

Background: Developing Good Clinical Practices (GCP) skills in early years of medical education markedly benefits medical students in taking part in research. The aim of the study is to improve medical students' skills for "from Writing the Research Protocol to presentation" training through engaging them in at least one research before graduation with this newly created sample of clinical research education model. The model will includes Experience-Based (ExBL), Team-Based (TBL) and rational "GCP Lesson" in the pre-graduate medical education curriculum in the future.

Methods: Third grade medical students were evaluated for two years with development of new GCP education model. A list over 500 drugs was created by using scientific sources and databases. The "Evaluation-Feedback Form" consisting of written feedback and questionnaire was prepared. The "QR-Code" application was used. The questionnaire study with 156 students was included. Both the new GCP model and research infrastructure were also explained. The helpful technological application was discussed.

Results: After this practice, many of the students (78.2%) found the lessons to be encouraging for future research. More than 75% of the students stated that they would like to take part in clinical research conducted in the future. The feedback shows that these practices increased self-confidence of participants (82.1%) and contributed to forming a young researcher community.

Conclusion: The necessity of allocating the share of students in the international research network and success of this model was reported. Including a reward system would support scientific research on the model's benefits to the students.

2

ABBREVIATIONS

GCP; Good Clinical Practices, Educators Abbreviation; AOG; Ali Osman Gürol, MD; Meral Demir, NB; Nerses Bebek, PS; Pınar Saip, TT; Tufan Tükek, VK; Vakur Akkaya, YD; Yavuz Dizdar. Edu; Educator/s, Min; Minute, SN; Student Numbers, Stu; Student.

3 BACKGROUND

The addition of a new lesson to the curriculum

The need for the placement of a care-clinical research curriculum in medical education was an ongoing international issue [1]. In Turkey, the “*Good Clinical Practices (GCP) Lesson*” related to clinical research [2], was not included in the curriculum of pre-graduate medical education. However, in post-graduate medical education, the basic education of GCP is provided for all parties. This education is necessary for both the formation of a researcher identity and for area specific use in students’ future careers. For instance, “*GCP Education*” has been provided in specific fields, such as for training the Members and Candidates of the Clinical Research Ethics Committee with the permission and participation of the Ministry of Health, Turkish Medicines and Medical Devices Agency [3]. This education is held in accordance with legal regulations and program content, and is conducted in cooperation with faculty, officials of institutes, research centers, health authorities (such as the Turkish Medicines and Medical Devices Agency and the General Directorate of Health Services), The Scientific and Technological Research Council of Turkey, other public institutions and organizations, as well as sponsors (clinical research companies, pharmaceutical companies, contracting research organizations, other industry organizations, and other funding sources).

The first studies on this educational model and long-term educational programs were prepared at the department of Medical and Clinical Pharmacology by Yağız Üresin (YÜ), Meral Demir (MD), and the educators in these practices in 2011. This model also provides the translational education in each area by involving all parties. Studies on including GCP Lesson in the pre-graduate medical education curriculum were carried out at relevant university departments. Following radical changes in the health system, options and consensus shaped the studies and meetings on whether new research infrastructures should be formed within the university, if necessary. The outcome of the meetings demonstrated a need to include students in clinical research, while including other researchers and employees. Moreover, clinical research training for Medical and Clinical Pharmacology should be included in the curriculum in earlier years of the medical education, following the recommendation of the department of Medical Education to implement it on the third semester. The idea of inclusion of “GCP Lesson” into the curriculum was firstly brought to the agenda in the 2015-2016 academic year, followed by studies conducted at the department. Since 2015, the educators have been taking the necessary steps, such as submitting a project proposal for of the European Union (EU) to include this lesson into curriculum. Dean of school has been part of the project meetings.

Content of the practices

In clinical research practices, enriching practices contents with effectiveness and safety issues is gaining more and more importance. The pharmacovigilance is defined as the activities and studies that are carried out for the identification, evaluation, understanding, and prevention of adverse

(unwanted) reactions. It is related to other drug problems in volunteers in clinical studies and constitutes the subfield of the multidisciplinary area of Medical and Clinical Pharmacology [4-6]. In 1968, a pooling system for collection of information, as well as other center for drug monitoring and safer use of medicine were established by the World Health Organization (WHO) [4,5]. The field on development of personalized treatment options has preserved its importance and grew with new developments [6]. The significance of drug safety is particularly important. An increase in unwanted reactions due to newly developed and routinely used medicines and side effects are widely studied in post-marketing pharmacovigilance studies. The inadequate level of clinical studies on pharmacogenetics might be a reason for the increase in unwanted reactions. The new “*Pharmacogenovigilance*” concept came about to prevent unwanted reactions that are 70% preventable [4-6].

In recent years, another safety issue is herbal products. The limited amount of clinical research in this area poses a risk for drug molecules to develop [7]. Therefore, an alternative medicine method, such as “*traditional and complementary*” should be discussed in evidence-based medicine, where clinical research is required for safety.

Due to legal regulations, safety warnings, for instance regarding unwanted events and effects, must immediately be reported to the relevant medical research center periodically. Safety of ongoing clinical research is a widely agreed topic in pre- and post-licensing [3-11].

All these reasons make case presentation, practice content enrichment with national and international clinical research important contents to be added to the curriculum.

Creating resources for practice

Books, e-books, academic, and regular documents related to GCP [2,8-13], and drug databases are recommended resources. A sample of a drug database, proposed for the first time by the department of Medical and Clinical Pharmacology in the Istanbul University Faculty of Medicine, went online in 2013. The database enables quick access to current drug indications, doses, unwanted effects for users at the university and outside for various purposes [13]. Other medicine databases are widely used as facilitators in these practices, and highly recommended for the students [14].

Developing a practices evaluation model

There is an increasing need for medical students to improve their GCP skills. The proposed model, aimed at improving GCP skills, is enriched with clinical experience. To improve the model, it is beneficial to measure student satisfaction [15], desire and response to the model, as well as to measure their skills in critical thinking, academic understanding, comprehensive clinical research methods and raise awareness in this field. There is currently no valid and reliable scale developed to determine student attitudes in this area. An attitude study in this field would increase research incentives through increasing self-confidence, facilitation of new research ideas, and scientific thinking. Thus, developing an evaluation criterion is a need. Educators are also work conducting on this subject.

Targets and evaluation

The primary goal in these practices was to demonstrate the importance of clinical research, to explain accurate and rational research designs with examples in the context of safety and efficacy, to involve students who were particularly interested in clinical research, and to guide them to develop a new research idea. Secondly, we aimed to include the “*GCP Lesson*” in the pre-graduate curriculum, ensuring coordination with other science lessons. Such coordination would enable students to complete the “*GCP Basic Education*” as a course with educators with “*Certificate of Achievement*” (Table 1). Student’s attitudes towards clinical research vary according to their learning styles. A pilot study on spring semester student presentations on clinical experience might be the first part of the research. Verbal and written feedback received by the educators during these practices is important for future research.

The second goal of the educational model is to introduce a development of evaluation model in Medical and Clinical Pharmacology in order to clearly learn the current interests, behaviors, and attitudes of students, in which the students would constitute the sample in the educational model. These Information Technologies (IT), used for a long time in drug security systems and patient services, would standardize quality of education on such practices (Table 2) [16-19]. The e-book discusses the outcomes of the two-term practices within the framework of teaching and learning targets.

Table 1: Teaching and learning objectives.









A. Teaching Objectives

1	Explaining the importance of clinical research and providing basic education with these practice lessons.
2	Giving general information about preclinical phases and to convey future expectations.
3	Giving general information about clinical research designs.
4	Explanation of the correct and rational designs of clinical research in the context of efficacy and safety. (Together with examples)
5	In particular, explanation of the assesment of safety drug clinical trials.
6	Explaining the approach to healty and sick participants in clinical research.
7	Describing the clinical research protocol in detail and explaining keypoints for writing a clinical research protocol.
8	Sharing information and experiences about the analysis and interpretation of clinical research outcomes.
9	Sharing information on the summary of the infrastructure works like research centers.
10	Sharing examples from national/international, single-center/multi-center research designs.
11	Explaining the approach of the industry (Contract research organizations, sponsor etc.) in clinical research.
12	Explaining the approach of public institutions and organizations in clinical research.
13	Sharing of scientific activity examples and explaining the forms of finalization of the research for student to gain the ability to create a perspective.
14	Improving the assesment and presentation skills.
15	Ensuring that students benefit from the right sources, such as article screening, international clinical research, medical books to reflect the suitable format for the presentation.
16	Explaining the basic criteria of being a good researcher.
17	Encouraging our students in the Future Medicine by sharing the expectations
18	Explanation of basic training in good clinical practice to educate young researchers with this training model.

B. Learning Objectives

- Expecting the students to have basic knowledge abot clinical research.
- Expecting them to learn the research opportunities at our university.
- Expecting that they will be able to develop new research ideas and create positive environment for them to take in a research.
- Expecting that they will create request for participation to be involved in a clinical research until they can graduate from medical education.
- Realizing the importance of philosophy along with science, In order to be a good researcher;
- Expecting that they could start and preliminary preparation for creating at least one scientific activity such as article, review, case presentation, poster.

Table 2: QR- Code applications and corresponding e-mail address.

Subgroup Number	A -Group Name and Qr- Code	Subgroup Number	B -Group Name and Qr- Code
1	M 16 / A 1 (a1+a2) / 15.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices / Evaluation with questionnaire 	5	M 23 / B 1 (b1+b2) / 15.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices / Evaluation with questionnaire 
2	M 16 / A 1 (a3+a4) / 14.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices / Evaluation with questionnaire 	6	M 23 / B 1 (b3+b4) / 14.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices / Evaluation with questionnaire 
3	M 18 / A 2 (a5+a6) / 15.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices / Evaluation with questionnaire 	7	M 25 / B 2 (b5+b6) / 15.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices / Evaluation with questionnaire 
4	M 18 / A 2 (a7+a8) / 14.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices/ Evaluation with questionnaire 	8	M 25 / B 2 (b7+b8) / 14.30 / IU / IFM Department of Medical and Clinical Pharmacology / 2016-2017 Spring Semester / 3rd grade Practices / Evaluation with questionnaire 

IU: Istanbul University; IFM: Istanbul Faculty of Medicine; M: May

4

MATERIALS AND METHODS

In this e-book, the evaluation of two-term practices was performed together. Among the measurement and evaluation techniques based on different methods, and evaluation study were discussed in two sections.

Content of lesson and resources

The implementation plan and program of this period, as well as resources utilized in the model were designed and created in accordance with the teaching objectives. The program also enables the willing students to take part in at least one clinical research that is currently ongoing and/or planned for future pre-graduate medicines and other products (Tables 1-5). In the practical phase, printed books [8], that are milestones of Medical and Clinical Pharmacology were utilized together with e-books [12], that the educators have open access from the university library. Educators suggested that students use the school presentation as a resource in these practices. Drug databases were also recommended by educators.

In order to help the students to easily overcome professional barriers, to develop professional skills, and to be able to take part in the research network; the 2017 spring semester was designed as a new course. The course was coordinated with other clinics, and built on the previous year's course on efficacy in drug research. Spring 2017 course focused on safety with effectiveness (Figures 1,2).

First-semester education

The number of educators in the study increased. The content of the course was based on efficacy in drug research. These lessons started with the section on *"How to design research"*, continued with the clinical experiences of instructors, and complemented with examples.

The first part of the course, which was an introduction to clinical research, was *"Efficacy in Clinical Research"*. School presentations were announced where students were divided into groups of 20-23 for the Spring 2016 semester (Figure 1). In the independent studies conducted the previous year, students were randomly separated into subgroups and were interviewed. Based on the educator's permission, the information and experiences related to the clinical research were shared in these interviews in the form of video-images and voice recordings, including pre-prepared questions. The visits to the research centers were provided at the university. These *"Student Groupworks"* with the scientific and other research activities were completed in presentation form, using appropriate techniques. Then, the students were verbally evaluated by the educators. At the end of these presentations and evaluations, the students were asked to fill the *"Evaluation-Feedback Form"* issued by the educator MD.

Formal structure of the measurement and evaluation form of first-semester education

The evaluation form has three open-ended questions on describing emotions, thoughts and

Table 3: Screening drug, biological product, herbal product and evidence-based treatment methods for safety.

Name	Name	Name	Name
A	Bupivacaine	Deferiprone	Evolocumab
Abatacept	Buprenorphine	Deferoxamine	Ezetimibe
Acarbose	Burdock	Degarelix	F
Acetazolamide	Busulfan	Dehydrocolic acid	Famotidine
Acetohexamide	C	Denosumab	Famciclovir
Acetylcholine	Cabazitaxel	Deoxycholic acid	Ferric ammonium citrate
Acetylcysteine	Cabergoline	Desmopressin	Fesoterodine
Adalimumab	Calcitonin	Dexamethasone	Fexofenadine
Adapalene topical	Calcitriol	Dextromethorphan hydrobromide	Finasteride
Adenosine	Calcium folinate	Diazepam	Flavoxate
Adrenaline	Calcium glubionate	Diazoxide	Flecainide
Aldesleukin	Calcium lactate	Diclofenac	Fludrocortisone
Alendronate	Capsaicin topical	Dicyclomine	Flumazenil
Alirocumab	Captopril	Didanosine	Flunisolide
Aliskiren	Carbachol ophthalmic	Diethylstilbestrol	Fluoxetine
Allopurinol	Carbamazepine	Digitoxin	Fluphenazine
Alpha-tocopherol	Carbenoxolone	Digoxin	Flutamide
Alprazolam	Carbetapentane	Dihydrotachysterol	Fluticasone inhalation
Alprostadil	Carmustine	Diloxanide furoate	Fluvoxamine
Alteplase	Carnitine	Diltiazem	Folic acid
Aluminum hydroxide	Carvedilol	Dimenhydrinate	Foliotropin alpha
Amantadine	Casanthranol	Dinoprostone	Formaldehyde topical
Amiloride	Cefoxitin	Diphenhydramine	Formoterol
Amiodarone	Celiprolol	Diphenoxylate	Fosinopril
Amitriptyline	Cephalexin	Dipivefrin	Frovatriptan
Amlodipine	Certolizumab	Dipyridamole	Furosemide
Amoxicillin	Cherry	Dobutamine	G
Amphetamine	Chlorambucil	Docusate	Gaifenezine (Glyceryl gayacolate)
Amphotericin b	Chloramphenicol	Dofetilide	Galantamine
Anakinra	Chloroquine	Dolasetron	Gemcitabine
Anastrozole	Chlorpromazine	Domperidone	Gemeprost
Antazoline	Chlorpropamide	Donepezil	Gemfibrozil
Antilymphocytic globulin	Chlorthalidone	Dopamine	Gentamicin
Apomorphine	Cholecystokinin	Dorzolamide ophthalmic	Ginger
Aprepitant	Cholestyramine	Doxepin	Ginkgo biloba
Aprotinin	Chorionic gonadotropin	Doxycycline	Gliburid (Glibenclamide)
Aripiprazole	Ciclesonide	Doxylamine	Gliclazide
Ascorbic acid	Cilastatin	Dronedarone	Glimepiride
Aspirin	Cilostazol	Drosiprenone	Glipizide (Glidiazinamide)
Atazanavir	Cimetidine	Duloxetine	Gliquidone
Atomoxetine	Cinnamon oil/tea	E	Glucagon
Atorvastatin	Ciprofloxacin	Ecothiophate	Glucosamine
Atropine	Cisapride	Edoxaban	Glycopyrrolate
Attapulgit	Cisplatin	Enprostil	Golimumab
Aurothioglucose	Clindamycin	Entecavir	Goserelin
B	Clobutinol	Epalrestat	Grapefruit
Baclofen	Clomipramine	Ephedrine	H
BCG	Clopidogrel	Eplerenone	Haloperidol
Beclomethasone	Coagulation Factor IX	Epoetin alfa	Heparin
Bendamustine	Codeine	Epoetin beta	Hepatitis B immunoglobulin
Bendroflumethiazide	Colchicine	Epoetin theta	Hexachlorophene topical
Benzalkonium chloride topical	Colesevelam	Epoetin zeta	Hidralazine

Benzonatate	Corticotropin	Epoprostenol (Prostaciline)	Histamine
Beractant	Cortisone acetate	Eprosartan	Histrelin
Betahistine 8	Co-trimoxazole	Erdosteine	Homatropine ophthalmic
Betamethasone	Cromolyn	Ergonovine maleate	Hydrocodone bitartrate
Betazole (Pentagastrin)	Crotamiton topical	Ergotamine	Hydrocortisone
Bethanechol	Cryoinol topical	Erythromycin	Hydroxocobalamin
Bexarotene	Curcuma longa	Escitalopram	Hydroxyzine
Biotin	Cyanocobalamin	Eslicarbazepine a.	Hyoscine
Biperiden	Cyclophosphamide	Esmolol	Hyperbaric oxygen therapy
Bisacodyl	Cyclosporine	Estradiol	Hypericum perforatum
Bismuth subsalicylate	Cyproheptadine	Estramustine	I
Bisoprolol	Cyproterone	Ethinyl estradiol	Ibuprofen
Bleomycin	D	Etodolac	Ifosfamide
Bosentan	Dabigatran	Etomidate	Iloprost
Botulinum toxin type b	Dalfopristin	Etretinate	Imipenem
Bromhexine	Danazol	Evolocumab	Immunotherapy
Bromocriptine	Dantrolene	Etodolac	Indomethacin
Budesonide	Darbepoetin alfa	Etomidate	Insulin Lispro
	Dasatinib	Etretinate	Interferon alfa
Ipecac Syrup	Midazolam	Phytonadione	Sucralfate
Ipratropium	Mifepristone	Pilocarpine ophthalmic	Sulfasalazine
Iron Sorbitol	Miglitol	Pioglitazone	Sulfonamide
Iron Sulphate	Mint oil	Piroxicam	Sumatriptan
Isoniazid	Misoprostol	Pizotifen	T
Isosorbide nitrate	Mitoxantrone	Plaquenil	Tacrolimus
Isradipine	Moclobemid	Platanaceae	Tamoxifen
Ivabradine	Mometasone topical	Plicamycin	Tenoxicam
K	Montelukast	Polyethylene glycol (Macrogol)	Terbinafine topical
Ketanserin	Morello	Polymyxin b	Terbutaline
Ketoconazole	Morphine	Potassium iodate	Terfenadine
Ketotifen	N	Pralidoxime	Teriparatide
L	Naftidrofuryl	Pravastatin	Terpin
Labetalol	Naloxone	Praziquantel	Testolactone
Lactulose	Naltrexone	Prazosin	Testosterone
Lamivudine	Nandrolone	Prednicarbate topical	Tetrabenazine
Lamotrigine	Naphazoline ophthalmic	Prednisolone Sodium Phosphate	Theophylline
Lanreotide	Nateglinide	Prednisone	Thiamine
Lapatinib	Nedocromil aerosol	Premarin vaginal	Thioguanine
Latanoprost	Neostigmine	Prilocain	Thrombin Topical
Lenalidomide	Nesiritide	Primaquine	Thyme oil
Lepirudin	Niacin	Primidone	Tibolone
Levamisole	Niclosamide	Procainamide	Tiotropium
Levetiracetam	Nicorandil	Promethazine	Tirofiban
Levodopa	Nicotine	Propafenone	Tizanidine
Levodropropizine	Nimodipine	Propranolol	Tocilizumab
Levofloxacin	Nitrazepam	Propylhexedrine nasal	Tolazamide
Levocetirizine	Nitric oxide	Propylthiouracil	Tolazoline
Levothyroxine	Nitrofurantoin	Protirelin	Tolbutamide
Lidocaine	Nitroglycerine	Prucalopride	Tolcapone
Linezolid	Nizatidine	Punica granatum	Tolvaptan
Lincomycin	Nonoxynol	Pyrantel	Topiramate
Liraglutide	Norepinephrine	Pyridostigmine	Topotecan
Lithium	Noretindron (Noretisterone)	Pyridoxine	Tramadol
Liothyronin	Nylidrin	R	Trandolapril
Lomustine	O	Radioactive iodine	Trastuzumab

Loratadine	Octreotide	Raloxifene	Treosulfan IV
Loperamide	Olanzapine	Ramipril	Tretinoin (Retinoic acid)
Losartan	Omeprazole	Ranitidine	Triamcinolone
Lubiprostone	Ondansetron	Ranolazine	Triazolam
M	Orlistat	Rasburicase	Trimethaphan
Magaldrate	Oxymetholone	Remifentanil	Trimethoprim
Malation topical	Oxymorphone	Repaglinide	Tripolidine
Mannitol	Oxytocin	Rezerpine	Tropicamide ophthalmic
Maraviroc	Q	Ribavirin	Tryptophan
Mazindol	Quinidine	Riboflavin	U
Mebeverine	Quercetin	Rifampin	Urofollitropin
Mecamylamine	Quazepam	Riluzole	Ursodiol
Mechlorethamine	P	Ritodrine	Urtica dioica
Meclizine	Palivizumab	Rituximab	V
Medroxyprogesterone	Pamidronate	Rivaroxaban	Valganciclovir
Mefenamik asid	Pancrelipase	Rivastigmine	Valproic acid
Megestrol	Pancuronium	Roflumilast	Vancomycin
Melphalan	Pantothenic acid	Rosuvastatin	Varenicline
Memantine	Papaverine	S	Varicella
Menadiol	Paraldehyde	Salbutamol	Vasopressin
Menadione	Paracetamol	Salmeterol	Venlafaxine
Meperidine	Paroxetine	Secretin	Verapamil
Mercaptopurine	Parsley oil	Selegiline	Veronica
Mestranol	Pegvisomant	Senna	Vinorelbine
Metformin	Pemetrexed	Sertraline	W
Methadone	Penicillamine	Sevelamer	Warfarin
Methimazole	Penicillin g benzine	Sevoflurane	Y
Methylcellulose	Pentobarbital	Sildenafil	Yohimbine
Methysergide	Pentoxifylline	Silver sulphadiazine topical	Z
Methocarbamol	Permethrin topical	Sitagliptin	Zafirlukast
Methotrexate	Phenelzine	Sodium bicarbonate	Zaleplon
Metoclopramide	Phenindione	Spectinomycin	Zanamivir
Metoprolol	Phenmetrazine	Spironolactone	Zidovudine
Metirosine	Phenobarbital	Streptokinase	Zileuton
Metronidazole	Phenytoin	Streptomycin	Zolpidem

* Designed in alphabetical order.

Table 4: A and B Subgroups, students number, selected schoolwork and presentations.

A-sub-groups Number	School works Name	Stu-dents Number	School works Name	Stu-dents Number	School works Name	Stu-dents Number	School works Name	Stu-dents Number
1	Colchicine	5	Diltiazem	5	Carbamazepine	5	Amoxicillin	5
2	Methotrexate	5	Amiodarone	5	Amphetamine	5	Sitagliptin	5
3	Quercetin	5	Bosentan	5	Fluoxetine	5	Metformin	5
4	Cilostazol	5	Digoxin	5	Tryptophan	5	Ketoconazole	5
5	Triamcinolone	5	Labetalol	5	Duloxetine	6	Penicillin	5
6	Allopurinol	5	Warfarin	6	Clomipramine	6	Sertraline	6
7	Plaquenil	5	Ezetimibe	6	Ecitalopram	6	Morphin	6
8	Adalimumab	5	Gemfibrozil	6	Flumazenil	6	Insülin	6
9	Cyclosporin	6	Carvedilol	6	Amantadine	6	Potassium	6
10	Certolizumab	6	Colesevelam	6	Diazepam	6	Adrenaline	6
11	Burdock	6	Hypericum perforatum	6	Senna	6	Ginkgo Biloba	6

12	Cherry and Morello	6	Veronica	6	Thyme oil	6	Mint oil	6
B-sub-groups Number	Schoolworks Name	Students Number	Schoolworks Name	Students Number	Schoolworks Name	Students Number	Schoolworks Name	Students Number
1	Atazanavir & Lamotrigine	5	Aspirin	5	Methimazole	5	Goserelin	5
2	Dofetilide & Lamotrigine	5	Atorvastatin	5	Imipenem	5	Prednizone	5
3	Tacrolimus & Phenobarbital	5	Dabigatran	5	Ceftiraxone	5	Ifosfamide	5
4	Rivaroxaban & Primidone	5	Edoxaban	5	Metoprolol	5	Mechlorethamine	5
5	Meropenem & Valproic acid	5	Rosuvastatin	5	Spiranolactone	5	Plicamycin	5
6	Zolpidem & Topiramate	6	Rivaroxaban	5	Furosemide	6	Cyclophosphamide	6
7	Aripiprazole & Topiramate	6	Cholestyramine	6	Salbutamol	6	Lapatinib	6
8	Isoniazid & Phenytoin	6	Losartan	6	Levosetirizine	6	Trastuzumab	6
9	Amitriptyline & Eslicarbazepine a.	6	Dronedaron	6	Dexamethasone	6	Anastrozole	6
10	Methotrexate & Levetiracetam	6	Quinidine	6	Omeprazole	6	Tamoxifen	6
11	Alprazolam & Grapefruit	6	Punica granatum	6	Curcuma longa	6	Parsley oil	6
12	Hijama	6	Platanaceae	6	Cinnamon oil/tea	6	Urtica dioica	6

Table 5: Research Topics.

Number	Research Topics
1	Antibiotics
2	Antineoplastic Drugs
3	Cardiovascular System Drugs
4	Drugs for fluid and electrolyte balance
5	Central Nervous System Drugs
6	Respiratory System Drugs
7	Endocrine System Drugs
8	Autonomic Nervous System Drugs
9	Digestive System Drugs
10	Autocoids
11	Antianemic Drugs
12	Vitamins, Retinoids
13	Medical Herbal Products and Alternative Medicine Practice

behaviors. At the end of the lesson, group interviews were conducted. According to the results of these evaluations, the preparations for the next term (period) were initiated (Table 6).

Second-semester education

In Spring 2017, as in the previous year, eight (8) groups of students received lessons in a total of 24 hours (Figure 2). The number of educators increased in 2017 and the content of the main topic was “*Safety in Clinical Research*”. These lessons started in accordance with the section on “*How to design research, how to create a research protocol, the calculation of sample size, statistical analysis, how to evaluate outcomes, how*

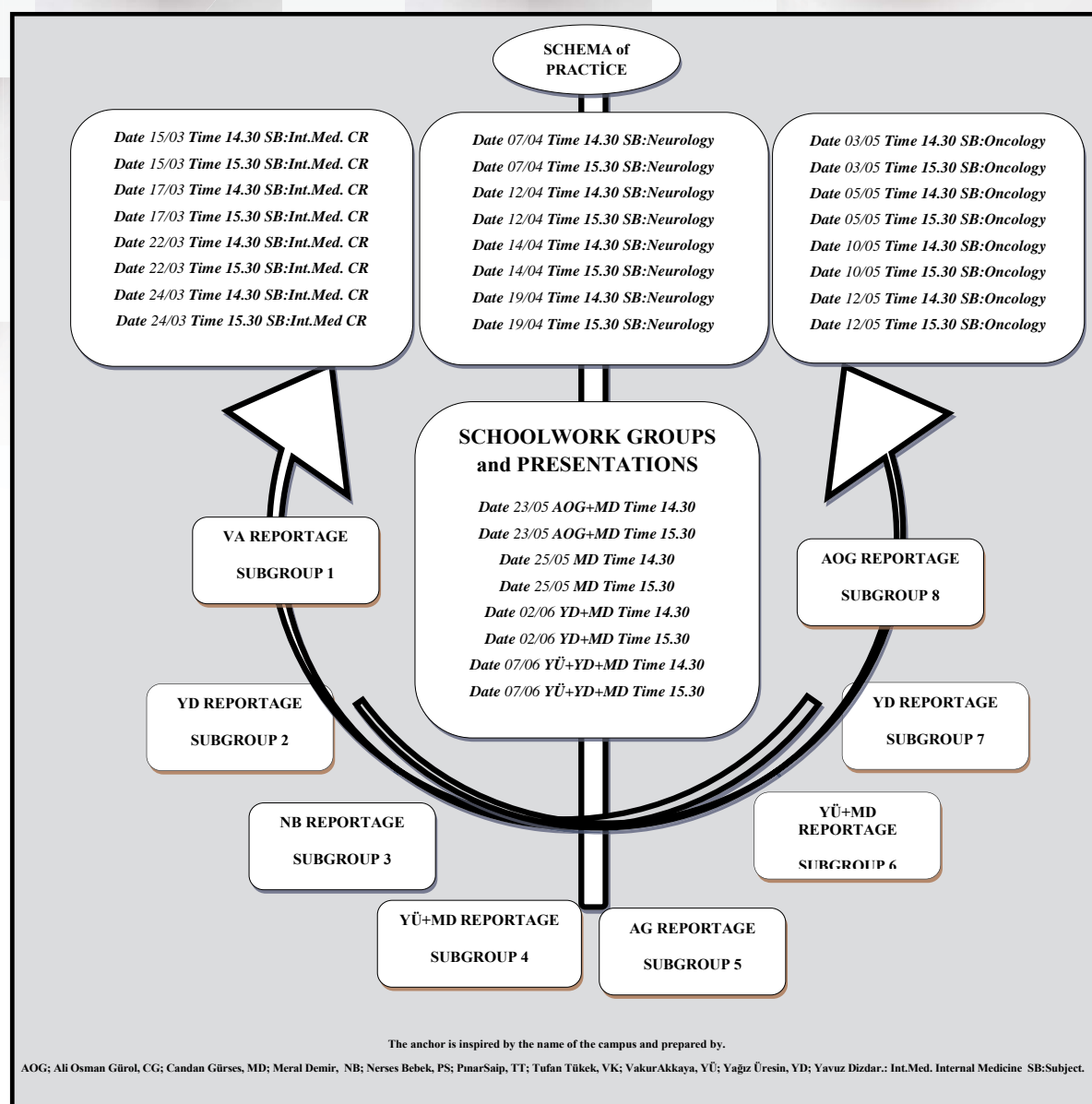


Figure 1: 2015-2016 Spring semester for Medical and Clinical Pharmacology Practice, schoolworks, educators, dates for third grade.

to obtain scientific activity (such as articles, posters, etc.), and how to finalize research". The course continued with educators' clinical experiences and were complemented with examples. In these lessons, the educators shared their experiences regarding drug development phases and drug clinical trials, with particular focus on neuropsychiatry, internal medicine, and oncology. The educators held interactive discussions with the students on "unwanted events", "unwanted effects", "unwanted drug reactions" and "side effects" that they encountered during clinical research.

More than 500 medicines and herbal products related to "Safety" were scanned from the relevant books, e-books, and databases for the assignment. Preliminary preparation required creating a list of general drug, biological, and herbal products by the educator MD. All educators made selections from the list (Tables 3,5) [8,12-14,16]. The number of third grade students in the course was 537, and the number of subgroup was 8 in Spring 2017. Each of these subgroups had between 60 and 70 students. Each subgroup was divided into smaller sub-groups of 5 to 6 students. Seven subgroups were given 10 drugs, 2 herbal products. One of the eight subgroups was given 18 drugs, 1 herbal product and 1 alternative medicine method relevant to the

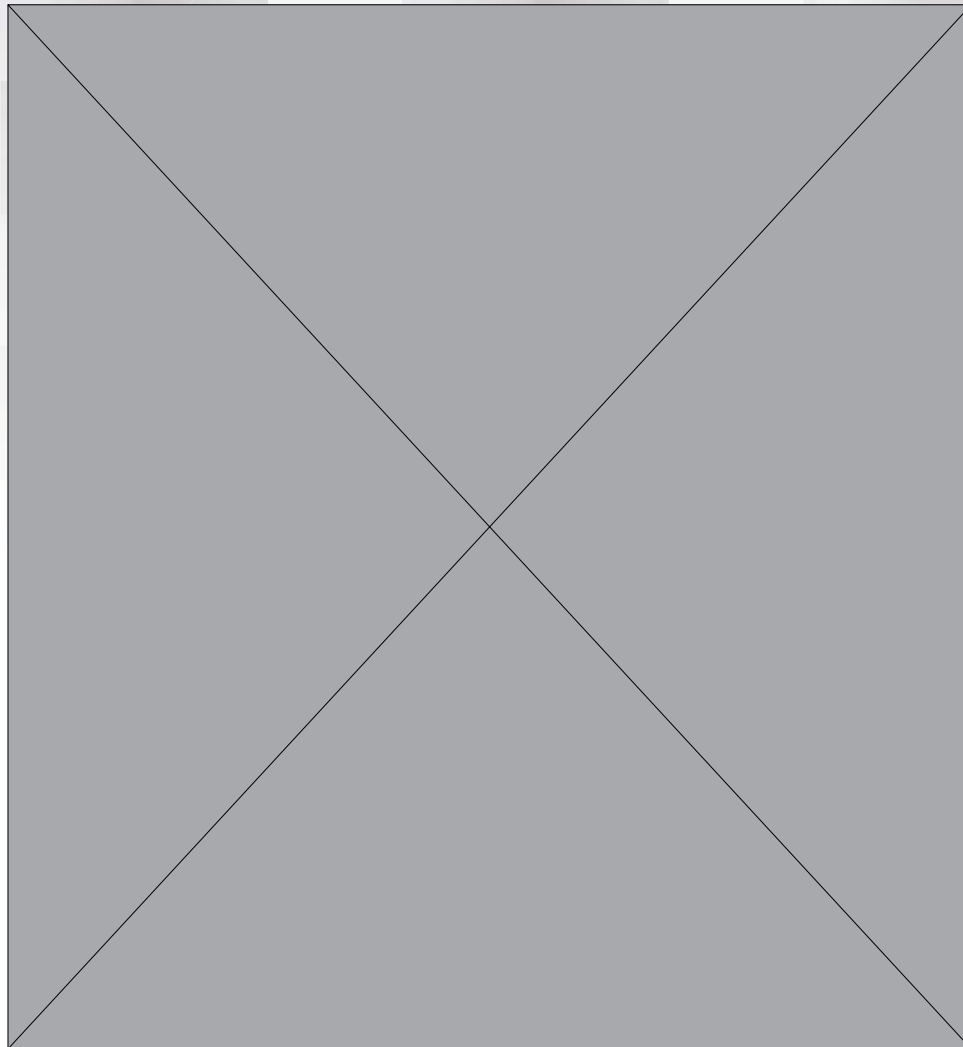


Figure 2: 2016-2017 Spring semester for Medical and Clinical Pharmacology Practice. 2016-2017 Spring semester for Medical and Clinical Pharmacology Practice.

interactions. In total, there were 12 assignments issued for school presentations to each subgroup (Table 4). These practices make students to go to the relevant poly/clinics and research centers and do not limit their researches to article, book, e-book and database scanning, but also allow them to come to us whenever they need; such practices were designed by the educators.

In the academic year 2016-2017, the educators created 96 different presentation titles from which students could select to make various forms of presentations (dramatization, Power Point presentation, etc.) at the end of the semester. The educators created a table that included all the students (Table 4). The titles of the schoolwork were shared with the students at the beginning of the semester and they were posted on the lectern board in the form of tables. The educators' expectations for schoolwork presentations were explained to the students in the form of a Power Point (ppt) before the start of lessons by the educator MD.

The student presentations were carried out by obtaining the demands of the students and evaluated by the educators at the end of the presentation lessons. As in the other year, in this year's program, the educators gave the books and the photographs as gifts to the students at the end of the lessons. Following the lessons and presentations, a "*Questionnaire Study*" was planned in order to obtain feedback from the students to evaluate these practices, create positive outcomes in the future, and ensure development.

Formal structure of the measurement and evaluation form of second-term education

The “*Questionnaire Study*” had three parts in total: preliminary evaluation of the scientific activities, in which the student participated before this practice (Table 7) with consisted of closed-ended three questions;; feedback, in which lessons were assessed and students proposed questions such as what clinical research they wanted to take part in in the future (Table 8) with consisted of closed-ended two, opened-ended one and Likert-type five questions;; and evaluation of the groupwork, which related to the presentations that the educators present to the students (Table 9) with consisted of Likert-type eight and opened-ended ne questions.

In addition, in the department of Medical and Clinical Pharmacology, thanks to the electronic applications (mail-based questionnaire and QR-Code) the students were able to respond to the questions in a very short time (Table 2). The mail address [19,20], was defined with the help of the Measurement and Evaluation Unit of the Istanbul University Faculty of Medicine and questions that were prepared by the educator MD for the questionnaire study were submitted to the online questionnaire study draft and transferred. It was arranged so that many students could easily answer each question in 2-3 minutes. This questionnaire saved time, as the students could access it with QR-Code applications Thus, they were able to answer the questions easily via mobile phones [21]. In terms of fast control and quality assurance, access to the questionnaire was limited to one hour. Applications were also created for each group (Table 2), and the printed documents were made available in the presentation rooms and amphitheater. Students participated in the questionnaire at the end of each group presentation.

The questions in the questionnaire were prepared by the educator MD and were pre-shared with all relevant educators for approval before being implemented. The drug and herbal products, and other relevant alternative medicine methods given as schoolwork selections were carried out together with all educators in accordance with the subject differences (Tables 5-9).

Table 6: Result of Evaluation-Feedback Form with response rate.

	Questions	Answers (N=97)
1	Whether these schoolwork presentations would contribute to the research that they will undertake in the future?	Yes Yes, definitely Yes, it will be a positive contribution Yes, it will help my academic career target I will sure to provide it We will develop more and find themselves in these research Yes, it was a great experience to talk to the community and give a presentation
2	Please, explain the aspects they like and/or lacked in these lessons and presentations.	I think it was very useful No other lesson has mentioned this topic It was a guide in taking steps to those interested in research In one word, it was magnificent There was nothing I found missing It was great and instructive Thank you very much for being so helpful and inviting clinicians to the lessons The presentations were helpful and developer The presentation was great, a discussion environment was created afterwards, and the topics were made to be digested The duration and style of the presentations was very good There was no deficiency Each layout was in place, their friends were very well prepared for their presentations, it was very enjoyable to listen and it offered a broader horizon The practice was nice because it was interactive Other medical and clinical lesson should be carried out like this practice
3	Please, write new ideas and recommendations.	It was nice to support the students I think everything was sufficient It was encouraging for students to attend the lessons and focus an interactive lessons The lessons and schoolwork presentations should continue in this way

Table 7: Results of preliminary evaluation with response rate in questionnaire.

Questions	Response Rate N(%)	Total Response Rate N(%)
Please mark the preclinical research that you have taken place before these lessons.		
In vitro	6(3.9)	153(98.1)
In vivo	9(5.8)	
Ex vivo	2(1.3)	
I didn't participate in the research	139(90.3)	
Please mark the clinical research that you have taken place before these lessons.		
National	8(5.2)	153(98.1)
International	4(2.6)	
Multi-center	2(1.3)	
Single-center	7(4.5)	
Retrospective	6(3.9)	
Prospective	3(2.0)	
Non-intervational clinical research		
Experimental clinical research	4(2.6)	
Questionnaire study	7(4.5)	
Genetic research other than gene therapy	2(1.3)	
Case / event (control)	8(5.2)	
Drug clinical trials and research	-	
Phase 1	-	
Phase 2	-	
Phase 3	-	
Phase 4	-	
Observational	2(1.3)	
Bioavailability/Bioequivalence	-	
Medical devices clinical research	-	
Medical devices	-	
Observational medical devices	-	
I didn't participate in the research	118(75.6)	
Please, mark your scientific presentation/s that you have been successfully completed before these lessons.		
Article	13(8.3)	155(99.4)
Review	7(4.5)	
Case report	17(10.9)	
Poster/ Oral presentation	18(11.5)	
Registry/ Patent	1(0.6)	
None	113(72.4)	

N: The numerical value of the students participating in the questionnaire In total's; %: Percentage of students who participated in the questionnaire. All questions have different answer options in the part.

Table 8: Feedback result with response rate in questionnaire.

Questions	Response Rate N(%)	Total Response Rate N(%)
These lessons were instructive and encouraging to take research in the future. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	34(21.8) 88(56.4) 20(12.8) 5(3.2) 9(5.8)	156(100)
New idea/s have been formed with the sharing of clinical experiences in these lessons by the educators. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	28(18.1) 74(47.7) 37(23.9) 10(6.5) 6(3.9)	155(99.4)
These lessons helped to create career goals. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	24(15.4) 63(40.4) 39(28.0) 22(14.1) 8(5.1)	156(100)
After these lessons, I want to take part in clinical research to be made in the future. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	39(5.0) 79(50.6) 27(17.3) 5(3.2) 6(3.8)	156(100)
If your answer is yes; please check which clinical research you would like to take place after these lessons. * Drug clinical trials and research Medical Devices clinical research Non-intervational clinical research Surgical clinical research (non-drug) Observational clinical research (drug, medical device)	58(43.0) 23(17.0) 26(19.3) 49(36.3) 43(31.9)	135(86.5)
If your answer is yes; please select the parties you wish to take part in clinical research in the future. † Principal/ Co-/Sub- investigator Representative of health authority (TMMDA) Representative of sponsor (supporting) Representative of contract research organizations (CROs) Member of Ethics Committee	108(78.8) 22(16.1) 13(9.5) 9(6.6) 30(21.9)	137(87.8)
During your studentship time, would you like to work as a "Support Personnel" in future clinical research. I agree completely I agree I undecided (Neither agree nor disagree) I disagree I disagree completely	46(30.5) 56(36.6) 33(21.6) 13(8.5) 5(3.3)	153(98.1)
N: The numerical value of the students participating in the questionnaire in total; %: Percentage of students who participated in the survey; TMMDA: Turkey Medicines and Medical Devices Agency; *and†: The answer options are different from the other questions.		

Table 9: Evaluation results of group study with response rate in questionnaire.

Questions	Response Rate N(%)	Total Response Rate N(%)
Before the schoolwork presentations, the theoretical content helped me to prepare schoolwork given by the educators. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	21(13.7) 74(48.5) 29(19.0) 22(14.4) 7(4.6)	153(98.1)
During the presentations preparation, I received enough scientific support from the educators. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	24(15.7) 47(30.8) 51(33.3) 24(15.7) 7(4.6)	153(98.1)
The team that I worked with for this schoolwork and presentations, in the lesson was very compatible. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	63(41.4) 52(34.2) 14(9.2) 13(8.6) 10(6.6)	152(97.4)
All members of our team contributed on working to the related schoolwork and presentations. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	69(45.4) 37(24.3) 14(9.2) 16(10.5) 16(10.5)	152(97.4)
The schoolwork and presentations helped to build self-confidence for the doing research. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	38(25.1) 86(57.0) 17(11.3) 6(4.0) 4(2.6)	152(97.4)
I think that the schoolwork and presentations will be useful to us in terms of prepare presentation and building presenting techniques in the future. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	60(39.5) 72(47.4) 13(8.6) 4(2.6) 3(2.0)	151(96.8)
The schoolwork and presentations, will enable to gain experience in the field of clinical research to contribute with the research that will be done in the future. I agree completely I agree Neither agree nor disagree I disagree I disagree completely	41(27.0) 74(48.7) 26(17.1) 8(5.3) 3(2.0)	152(97.4)
I would like the educators to convert the schoolwork and presentations together with the other groups into a 2 day programme as "Student Activity/Presentation Festival". I agree completely I agree Neither agree nor disagree I disagree I disagree completely	39(25.7) 33(21.7) 35(23.0) 34(22.4) 11(2.2)	152(97.4)
N: The numerical value of the students participating in the questionnaire in total; %: Percentage of students who participated in the questionnaire		

Statistical analyses

"Cross-sectional research" method was preferred for data collection and classification. Item, validity and reliability analyzes were performed of the questionnaire study. SPSS 21.0 Package program was used for all statistical analysis. A comparison was made between the groups that participated in the preclinical or clinical trial and those who did not ([Appendix e-1](#)).

Table 10: Answers of 20th and 11th Items in Questionnaire Study.

Questions	Answers
1 Whether these schoolwork presentations would contribute to the research that they will undertake in the future?	<p>Yes</p> <p>Yes, definitely</p> <p>Yes, it will be a positive contribution</p> <p>Yes, it will help my academic career target</p> <p>I will sure to provide it</p> <p>We will develop more and find themselves in these research</p> <p>Yes, it was a great experience to talk to the community and give a presentation</p>
2 Please, explain the aspects they like and/or lacked in these lessons and presentations.	<p>I think it was very useful</p> <p>No other lesson has mentioned this topic</p> <p>It was a guide in taking steps to those interested in research</p> <p>In one word, it was magnificent</p> <p>There was nothing I found missing</p> <p>It was great and instructive</p> <p>Thank you very much for being so helpful and inviting clinicians to the lessons</p> <p>The presentations were helpful and developer</p> <p>The presentation was great, a discussion environment was created afterwards, and the topics were made to be digested</p> <p>The duration and style of the presentations was very good</p> <p>There was no deficiency</p> <p>Each layout was in place, their friends were very well prepared for their presentations, it was very enjoyable to listen and it offered a broader horizon</p> <p>The practice was nice because it was interactive</p> <p>Other medical and clinical lesson should be carried out like this practice</p>
3 Please, write new ideas and recommendations.	<p>It was nice to support the students</p> <p>I think everything was sufficient</p> <p>It was encouraging for students to attend the lessons and focus an interactive lessons</p> <p>The lessons and schoolwork presentations should continue in this way</p>

Table 10: Answers of 20th and 11th Items in Questionnaire Study.

Questions	Answers
1 Whether these schoolwork presentations would contribute to the research that they will undertake in the future?	<p>Yes</p> <p>Yes, definitely</p> <p>Yes, it will be a positive contribution</p> <p>Yes, it will help my academic career target</p> <p>I will sure to provide it</p> <p>We will develop more and find themselves in these research</p> <p>Yes, it was a great experience to talk to the community and give a presentation</p>
2 Please, explain the aspects they like and/or lacked in these lessons and presentations.	<p>I think it was very useful</p> <p>No other lesson has mentioned this topic</p> <p>It was a guide in taking steps to those interested in research</p> <p>In one word, it was magnificent</p> <p>There was nothing I found missing</p> <p>It was great and instructive</p> <p>Thank you very much for being so helpful and inviting clinicians to the lessons</p> <p>The presentations were helpful and developer</p> <p>The presentation was great, a discussion environment was created afterwards, and the topics were made to be digested</p> <p>The duration and style of the presentations was very good</p> <p>There was no deficiency</p> <p>Each layout was in place, their friends were very well prepared for their presentations, it was very enjoyable to listen and it offered a broader horizon</p> <p>The practice was nice because it was interactive</p> <p>Other medical and clinical lesson should be carried out like this practice</p>
3 Please, write new ideas and recommendations.	<p>It was nice to support the students</p> <p>I think everything was sufficient</p> <p>It was encouraging for students to attend the lessons and focus an interactive lessons</p> <p>The lessons and schoolwork presentations should continue in this way</p>

5 RESULTS

Questionnaire Result

In the academic year 2015-2016, approximately 20 student groups made the presentations. Afterwards, a total of 97 students participated in the feedback by filling in a printed document. This number constitutes 20.0% of the students participating in the lessons. Table 6 shows the answers of the students to the “*Evaluation-Feedback Form*” at the end of their presentations. After this practice, many of the students (79.4%) thought that the presentations would contribute positively to their future research.

The students were satisfied with the time of presentations. However, there were students who wanted to have more time to make presentations. There were also suggestions to have fewer subgroups so that more students could prepare/participate in the presentation.

In the 2015-2016, 49 of the 96 schoolwork assignments that were presented by the student groups, more than 50% in total, were given in this limited time (8 lesson hours). Compared to the previous year, the students were given more than twice as many presentations. Each group was evaluated orally by the educators when the schoolwork presentations were over. Afterwards, a total of 156 students participated in the questionnaire. Of these students, 143 accessed the questionnaire online and 13 filled out a printed document. While this number constitutes 33.4% of the students participating in the lessons, it was expressed by 29% of the total number of students. Questionnaire results are summarized in Tables 7-9. After this practice, many of the students (78.2%) found the lessons to be encouraging for future research and more than 75% of the students stated that they would like to take part in clinical research conducted in the future. Many of the students (43%) expressed that they would like to take part in drug clinical research while many also preferred surgical research (36.3%). 78.8% of the students stated that they would like to work as a principal/co-/sub-investigator in clinical research that will be conducted in the future, while 21.9% of the students stated that they wanted to become members of the Ethics Committee. More than 75% of the students stated that they also wanted to work as “*Support Personnel*” in clinical research in the future (Table 8).

The compliance of the students to their groupwork was over 75%. The data shows a positive rate of 82.1%, suggesting that these presentations allowed them to gain self-confidence to conduct research. Also, 86.9% of the students thought that these presentations would be beneficial in the future-- in terms of providing them with the skills needed to prepare presentations and to learn presentation techniques. One of the best results of the questionnaire was that 75% of participants felt that this schoolwork study would allow students to gain experience in clinical research and to think about what they would do to contribute to research that they would conduct in the future (Table 9).

Incoming suggestions

In the questionnaire, the opinions and ideas in the form of five answers to 11th question, and ten answers to the 20th question were reported by the students (Table 10).

In addition, the KMO coefficient value was 0.864 and Barlett's Test of Sphericity ($p < 0.001$) was significant. (Cronbach's alpha) reliability coefficient was found to be 0.90. This value indicates that the scale degree is in "very good" for reliability. This variance value can be considered degree in "good".

There was no significant difference between the groups who participated in the preclinical or clinical research and those who did not participate, with and without scientific presentation ($p < 0.05$) ([Appendix e-1](#)).

6

DISCUSSION

Determination and evaluation of the subjects of the practices

The most common clinical trials and research in the world are documented by the numbers of registered clinical trials in internal medicine, oncology and neuropsychiatry. Since 2000, around 250,000 clinical research studies have been conducted around the world, most of them multi-centered. As of 2008, the final report of clinical research databases recorded. It can be scanned with sub-research topics and is updated regularly [22]. Clinical research databases have also been established in Turkey, and improvement studies are still ongoing. With these records and accompanying components, it was observed that the newest developments are required upon examination of global disease burden studies, the published long-term reports of WHO, and cancer incidence and mortality rates in the world [23-25]. In their cases, lesson program and schoolwork presentation activities are shown to be compatible with those of the clinical research areas that the educators are talking about.

It was shared for informational purposes for different clinical research that can be done with the example of “*Safety Test*,” the first creation point of which was a doctorate thesis. The owner of this thesis is also an educator in this practice [26]. An example of the start of clinical research and “*Different Safety Tests*” can be created so that it can be used in schoolwork presentations as a “*facilitator*” as they are in this thesis study. Different studies, however, can be made in order to standardize these tests. Moreover, “*Safety Clinical Research*” is not only used in clinical drug research but also as a whole in conjunction with medical device clinical research, surgical research, non-interventional, and other clinical research and should be planned and performed [27-28]. Therefore, unlike the previous year, along with efficacy, educators have been discussing the subject of safety more together with efficacy. In this context, it was considered to be useful for the educators to create a perspective for students.

Lesson load and satisfaction

The satisfaction of the lessons was high. The students expressed their satisfaction with the practice through the questionnaire and verbally. Students also had higher attendance and demonstrated desire to participate in more presentations. Another outcome was an increased desire to take part in the clinical research at the end of the practice, which proved that the course acted as an incentive for students to participate in.

Educational model and evaluation of group schoolwork

Team-Based Learning (TBL) is becoming an active learning strategy among health professionals. Modified studies lead to the development of many new practice areas. In Turkey, there are practices based on teamwork in educational models as well. However, it is difficult to find workshops on “*GCP Training*” after graduation, despite its proven contribution to the spread of academic research in

pre-graduate Medical Education.

There is a need to include strategies to develop co-operative skills in medical education. The model poses a solution as an active teaching strategy that may be conducted with groups of 5-7 students [29,30]. The process can be conducted one or more educators with the help of a specialist. The model in this study was created through this way as well [29]. Groups were randomly created by the educator [31-33] in the 2016-2017 academic year and was a successful method.

Practice activities are intended for teams to develop skills such as problem solving, case presentation, and teamwork. These practices, first implemented at the end of the 1970s, improve students' academic performance [34]. TBL is a learning-centered teaching strategy that is used in groups that receive health education, including "*Medical Students*". The findings demonstrate that the academic performance of students improved, where the students described TBL as a very constructive experience that encourages deeper learning. The study suggests using modified version of team-based learning, "*MTBL*," in university lessons more often [35]. In another study on medical students, students preferred TBL over traditional didactic narrative (theoretical) and the success rate was higher than in the traditional method [36]. The success of TBL demonstrates a higher appreciation among students for sharing of clinical experiences.

The individual performances directly affect team performance, as teams have the ability to discourage or encourage team members' work. Therefore, teams are an appealing "*Active Training Methods*" for educators [37]. In medical education, these methods were initiated with pilot practices in the 1990s. It has been determined that teamwork promotes out-of-class individual work and increases productivity through interpersonal interaction [31]. Nowadays, the samples in pre- and post-graduate education support this idea. The increase in these practices in Turkey and the dissemination of academic studies on this subject will provide valuable contributions to medical education. Publications and suggestions for teamwork usage in clinical lessons are also taking speed, in conjunction with Medical and Clinical Pharmacology [38].

It is a basic rule for students to come prepared to their educational practices. The participation of 461 students in the schoolwork presentation lessons and the preparation of all subgroups for the schoolwork presentations show that the educators provide this "*Basic Rule*". Students are expected to prepare and present assignments intended for gaining knowledge and/or skills. They have full responsibility for this process. The successful completion of the preparatory process is required to be able to benefit from the following stage. They are also assessed in the following stages as to whether they have reached this objective or not. The "*Scientific Activity/Festival*" recommendation may prove to be useful therefore in the future; students who are unable to make presentations in a progressive stage can be followed up on and evaluated.

Students are expected to perform both in a team and individually [32]. As seen in the positive findings, most of the students contribute. It is also shown that group discussions can be a useful educational method [31-33]. When considering its advantages and disadvantages in academic research, TBL is an effective training method. It should be more commonly used in medical education programs and planned correctly in the presence of highly motivated educators to become an effective learning method [31-33]. In the current study, by taking the clinical trial design into consideration, teams were divided into groups. Within framework of this model, lessons were prepared together with the educators in different clinics and evaluated together through school presentations. There is a need for student-educator collaboration in implementing clinical research content. Therefore, it is useful to study new IT databases that can be used in research so that each subgroup can provide their results to their educator. Other studies indicate that based on the physician perspective in clinical research on physician-patient relations, students wanted to take part in future clinical research and that the desire to work as "*Support Personnel*" in current clinical research was high. There are studies ongoing within the framework of creating a new, faster, and more active research base. In this context, the principal researchers will be able to assign students according to the study areas and their demands.

In self-sufficiency and peer assessment studies, self-sufficiency is defined as a constantly changing,

cognitive process that people “do” instead of a static quality that they “possess” [39]. These practices, which are models for educating physician researchers in medical departments, constitute a sample model for the future. The relationship between research and self-efficacy was analyzed through the career-related areas of interest of medical students, specialty and scholarships. It was suggested that the more medical students were exposed to research experiences, the more self-sufficiency they demonstrated [40]. These practices, which should be considered as a basis for the building of self-sufficiency, are valuable in terms of creating positive role models. Improving the clinical research skills of students can be linked to enhancing research motivation by transforming these advantages into self-fulfilling skills. All these results prove the success of this practice.

Gains and future goals

The educators were reported to reach the objectives and goal (Table 1) of these practices, which are necessary at the start of clinical research and allow for the emergence of a successful and very positive educational picture.

Unlike the previous year, the electronic applications that were used for evaluation for the first time have been utilized for a long time in health practices. It is believed that this method creates a beneficial model by also being used for *educational* purposes. It is a quick and easy method of assessment and evaluation [17-19,21].

Another positive outcome is that Yavuz Dizdar (YD) will be carrying out a further study at the end of this practice [41]. This program, which lasts 15 days at the end of the semester during the summer, was put into practice. Expressions that are important for art, philosophy and science are emphasized and taking part in other educational activities is among the criteria of being a good researcher (Table 1).

The Edinburgh Declaration of the World Federation for Medical Education, which aims to train competent future physicians who are able to use their knowledge in professional practices that inquire the future of pre-graduate education and bring solutions to problems, has shifted its focus. Instead of activities which encourage students, they seek to make students independent and guide themselves to methods which encourage one-on-one interaction between the educator and the student, ensuring life-long learning [42]. These requirements have gradually increased the interest in evaluations in medical education [43,44]. Studies oriented towards the development of clinical practice skills in medical education are also carried out using new tools [45]. The scientific lectures start with second year students in the light of the studies on the development of clinical logic ability by concentrating on the amygdala, which plays a role in the regulation of the long-term memory. The start of clinical research courses which allow students to interact with patients in the third grade and the incorporation of minor tasks and impressions in the early phase of clinical research allow us to believe that they will increase the success in future clinical practices. Moreover, they have reported the cognitive benefits of problem solving knowledge in a study conducted by comparing the re-occurrence of problems with (treatment approaches applied to similar patients). They have developed a hypothesis that the “problem-solving” issue in medical faculty students will cause a significant increase in brain region activities associated with higher cognitive functions, such as the Dorsolateral Prefrontal Cortex (DLPFC). Based on the intuition of physicians, the (fast and precise) repetition of clinical decision making experiences can improve their professional perception. It has been reported that in clinical work with medical students, the Functional Magnetic Resonance Imaging (fMRI) system is used to detect extreme oxygenated brain regions, to observe brain activities during certain cognitive processes and should be used as a promising tool in the investigation of clinical reasoning [46].

It is believed that a rational and adequate education program was created in terms of creating aptitude for and harmony in teamwork. Moreover, certain needs, such as the need for space for units and centers created for the university’s research infrastructure, are reduced, and factors that facilitate physician researcher productivity are increased. It is known that Medical and Clinical Pharmacology education modeling was established and applied depending on the need in the recent years [47]. Therefore, the addition of the new

"GCP Course" to the pre-graduate medical education curriculum will provide guidance among research lessons and will provide continuity in education along with curriculum mobility.

Therefore, certain necessities for making an early start in research to take an early step into the future arise. The provision of infrastructure and other requirements that may enable research is also important in terms of encouraging research [48]. Therefore, within the framework of the collaboration among institutions and organizations under the TUBITAK 2209/A project, which is another science-based program that supports university students, young researchers are provided opportunities and all parties are facilitated and provided an advantage at the university. Through new practices implemented by the Scientific Research Projects Unit (BAP) at the university, new support opportunities were created after receiving feedback from the educators [49].

Today, it is important for physician candidates to take part in the research network in the early years of their education and to carry out activities in this field. As a result of the evaluations, the educators present the view that the students can be involved in both education and research, and that they can come a great way with student Exchange (Erasmus) programs in the framework of international cooperation. For example, the "*European Union Jean Monnet Erasmus Program*" is a good example. The educator MD attended a meeting regarding this topic in 2016. This program, which may be a first at the university, presents the view that there will be very positive outcomes and achievements within the EU process. When this and other support opportunities are coupled, they make up the award system the educators mentioned before [50].

Experience-Based Learning (ExBL) is a comprehensive model of medical students' practice-based learning. It is suggested that clinical teaching in the 21st century" learning from real patients within clinical practice [51]. So, the skill of ExBL is to rise participating in practice well-organized learning environments where clinicians share their expertise for help to participate students as researcher within clinical research. In this context, this training model is considered to be a useful example model.

7 CONCLUSION

The value of these practices is understood when the incentives, which allow students - as well as candidates in specific areas - to start early in the research and participate in the clinical trial, provided by educators were evaluated. The fact that the students also obtain a researcher identity through this practice positively effects their communication with their patients. Moreover, the creation of this sense of identity allows them to gain self-confidence, stay motivated, and feel rewarded. This model increases the aptitude for and satisfaction of work done for vocational maturity and makes it easier to take part in a research team. In order to correctly reposition the students within clinical research through a rational and appropriate organization, the advantages of these types of practices should be taken into consideration. In this context, it can be said that the first steps in GCP basic education can be taken in pre-graduate medical education with this practices model, measurement and evaluation method, and also it can be said that the professional attitudes of students can be improved positively through such practices.

Ethics approval and consent to participate

The study was based on volunteer participation, the details of the study were explained to the participants and their verbal informed consent was taken prior to the assessment. As this study was outside the mandate of the Turkish Medicines and Medical Devices Agency (TMMDA), the Clinical Research Ethics Committee of Istanbul Medical Faculty determined in a written statement that no ethical approval was required for this study (Number:1383) [11].

Availability of data and materials

The datasets and materials used and/or analysed during final of the practices (schoolwork presentations) are available from the corresponding author and evaluated the total datasets at the end of the semesters. No personal information in provided in this study [11].

Competing interests

The author(s) declared no conflict of interest with respect to the research, authorship and/or publication of this e-book.

Author's contributions

MD all contributed to conception and the design of the study. MD was responsible for the data acquisition. MD analysed the data and drafted the e-book. MD, YD, NB, VA, TT, AOG and PS were an educator and a researcher in this practices. All authors selected schoolworks and evaluated the presentations. MD, YD, NB, VA, TT, AOG and PS read and controlled the e-bookdraft critically and then approved of the final version for publication.



ACKNOWLEDGEMENTS

We would like to thank our students (from Istanbul University, Istanbul Faculty of Medicine), Prof. Dr. Ahmet Gül (from Istanbul University, Istanbul Faculty of Medicine Department of Rheumatology), Prof. Dr. Aytaç Öncül (from Istanbul University, Istanbul Faculty of Medicine Department of Cardiology), Prof. Dr. Aykan Canberk (from Istanbul University, Istanbul Faculty of Medicine Department of Medical and Clinical Pharmacology), Prof. Dr. Yağız Üresin (from Istanbul University, Istanbul Faculty of Medicine Department of Medical and Clinical Pharmacology) and Prof. Dr. Candan Gürses (from Istanbul University, Istanbul Faculty of Medicine Department of Neurology) for their contributions on the practices.

We would like to thank Prof. Dr. Zeynep Solakoğlu (from Istanbul University, Istanbul Faculty of Medicine Department of Medical Education), Uğur Kuş (from Istanbul University Istanbul Faculty of Medicine Web Master) and Oya Vatansever (from Istanbul University, Istanbul Faculty of Medicine, Measurement and Evaluation Ideas Unit for Third Grade Students) for their contributions when preparing questionnaire study.

9 REFERENCES

- Murillo H, Reece EA, Snyderman R, Sung NS (2006) Meeting the challenges facing clinical research: solutions proposed by leaders of medical specialty and clinical research societies. *Acad Med* 81: 107-112. Link: <http://bit.ly/2rWFjx8>
- ICH- GCP Guidelines. Link: <http://bit.ly/35KCbmw>
- Good Clinical Practices Education Series in Turkey.
- Pharmacovigilance. World Health Organization. Link: <http://bit.ly/2PFrMmr>
- Uppsala Monitoring Centre. Who Collaborating Centre. World Health Organization. Link: <http://bit.ly/2SbD0kw>
- Sardaş S (2016) Pharmacogenovigilance. *Turkey Clinics. J Pharmacol* 4: 1-7. Link: <http://bit.ly/2PFdMsN>
- Karaalp A (2016) Herbal Products in terms of Promotion, Advertising and Information Ethic. Symposium by Turkey Medical Association. There is no Alternative of Medicine. Link: <http://bit.ly/2tuBeQW>
- Kayaalp O (2012) In terms of Rational Treatment. *Medical Pharmacology*.
- Implementing Regulation on the safety of drug and Good Pharmacovigilance Practices. Turkey Medicines and Medical Devices Agency, Department of Pharmacovigilance. <https://bit.ly/2Wuzfam>
- Regulation on the Clinical Research of Drug and Biological Products, the other implementing regulation and guidelines. Turkey Medicines and Medical Devices Agency, Department of Clinical Research. <https://bit.ly/2WtmCMA>
- Application conditions of Committee and related legal regulations. Clinical Research Ethics Committee of Istanbul Faculty of Medicine, Istanbul University. <https://bit.ly/2L0C7Gu>
- Openaccess e-book of Istanbul University. Department of Library and Documentation of Istanbul University. Link: <http://bit.ly/2Z6r0lu>
- Truven Health Analytics Micromedex Solutions. Drug Information Database. Link: <http://bit.ly/2EBmWjN>
- Openaccess Drug Information Database. <https://bit.ly/3fhV3hQ>
- Kenar İ, Balcı M (2012) The development of attitudes toward science and technology lesson scale: the case of 4th and 5th grade primary school student. *Dumlupınar University Journal of Social Sciences*.
- List of Herbal Product. Turkish Medicines and Medical Devices Agency. <https://bit.ly/2zVpBWf>
- Tseng MH, Wu HC. (2014). A cloud medication safety support system using QR code and Web services for elderly outpatients. *Technol Health Care*, 22(1): 99-113. <https://bit.ly/3b903IR>
- Aksu CK, Gelibolu L (2015) A research on determination of the attitudes of university employees towards sustainable consumption. *J Kağıt 6*: 235-248.
- Online Questionnaire e-mail addresses for this practices. t.farmakoloji.donem3@gmail.com
- Bujang MA, Omar DE, Baharum AN (2018) A Review on Sample Size Determination for Cronbach's Alpha Test: A Simple Guide for Researchers *Malays Journal Med Sci* November-December 25: 85-89. Link: <http://bit.ly/2PGkfEc>
- Example for QR Code Web Address. <https://bit.ly/3fosakb>
- Clinical Trials Database. Link: <http://bit.ly/2twYcXG>
- GBD 2015 Risk Factors Collaborators (2016) Global, regional and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risk factors or clusters of risks, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 8: 388: 1659-1724. Link: <http://bit.ly/2Z7ySDr>
- Ten years in public health, 2007–2017: report by Dr Margaret Chan, Director-General, World Health Organization. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. <https://bit.ly/2SCZVVi>
- Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, et al. (2015) Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *Cancer* 136: E359- E386. Link: <http://bit.ly/35IIA1x>
- Meral Demir's Doctorate Project. The place of new antiepileptic drugs and brain-derived neurotrophic serum levels in new antiepileptic efficacy and safety monitoring in Istanbul University. Link: <http://bit.ly/2Me34HY>
- Harvey AR, Basavaraju SV, Chung KW, Kuehnert MJ (2015) Transfusion-related adverse reactions reported to the National Healthcare Safety Network Hemovigilance

- Module, United States, 2010 to 2012. *Transfusion* 55: 709-718. Link: <http://bit.ly/2s3zCxa>
28. The licensing of human tissue and cell products and communicate about the centers that carry out production, import, export, storage and distribution activities of these products. Link: <http://bit.ly/2sN1RQG>
 29. Willett LR, Rosevear GC, Kim S. (2011). 'A Trial of Team-Based Versus Small-Group Learning for Second-Year Medical Students: Does the Size of the Small Group Make a Difference?', *Teaching and Learning in Medicine*, 23(1): 28. <https://bit.ly/3fpgjSZ>
 30. Altıntaş L, Alimoğlu MK, Altıntaş Ö, Bütün E, Ergüven S, et al. (2011) Evaluations of training practices conducted by team-based learning method. Abstract book of community-based medical education and training research symposium 45-46.
 31. Thompson BM, Schneider VF, Haidet P, Levine RE, McMahon KK, et al. (2007) Team-based learning at ten medical schools: two years later. *Med Educ* 41: 250–257. Link: <http://bit.ly/35KcuCs>
 32. Michaelsen LK, Black RH (1994). *Building Learning Teams: The Key to Harnessing the Power of Small Groups in Higher Education*. In *Collaborative Learning: A Sourcebook for Higher Education*, Vol. 2. pp. 65-81. State College, PA: National Center for Teaching, Learning & Assessment, 1994. <https://bit.ly/2L4Ekki>
 33. Thompson BM, Schneider VF, Haidet P, Perkowski LC, Richards BF (2007) Factors Influencing Implementation of Team-Based Learning in Health Sciences Education. *Acad Med* 82: S53–S56. Link: <http://bit.ly/2Mcrem7>
 34. Michealsen LK, Watson WE, Cragin JP, Fink LD (1982). Team-based learning: A potential solution to the problems of large classes. *Exchange: The Organizational Behavior Teaching Journal*, 7: 13-22. <https://bit.ly/3b7cEpz>
 35. Rania N, Rebora S, Migliorini Laura. (2015). Team-based Learning: Enhancing Academic Performance of Psychology Students. *Procedia -Social and Behavioral Sciences*, 174: 946–951. <https://bit.ly/3caf5cj>
 36. Michealsen LK, Peterson TO, Sweet M (2009) *Building Learning Teams: The Key to Harnessing the Power of Small Groups in Higher Education*. The SAGE Handbook of Management Learning. 325-343. Link: <http://bit.ly/2Zai8v7>
 37. Altıntaş L, Alimoğlu MK. (2016). Team-based Learning. *Türkiye Klinikleri J Med Educ Special Topics*, 1(1): 33-40. <https://bit.ly/3fs8wnh>
 38. Orme M, Sjöqvist F, Birkett D, Brøsen K, Cascorbi I, Gustafsson LL, Maxwell S, Rago L, Rawlins M, Reidenberg M, Smith T, Thuerman P, Walubo A. Journal compilation 2010 Nordic Pharmacological Society. *Clinical Pharmacology in Research, Teaching and Health Care. Basic & Clinical Pharmacology & Toxicology*, 107, 531–559. <https://bit.ly/2zis8JS>
 39. Cervone D (2000) Thinking About Self-Efficacy. *Behav Modif* 24: 30-56. Link: <http://bit.ly/2Z9lte7>
 40. Bierer SB, Prayson RA, Dannefer EF (2015) Association of research self-efficacy with medical student career interests, specialization, and scholarship: a case study. *Adv in Health Sci Educ* 20: 339–354.
 41. Dizdar Y. The sprouts that the new generation of curious seeds will turn into doctrine at Medicine; 2016 and Brain Team: "Next Generation"; 2017. Link: <http://bit.ly/390cRuH>
 42. World Health Organisation (1988) The Edinburgh Declaration. World Conference on Medical Education of the World Federation for Medical Education Edinburgh Scotland.
 43. Özcan S, Yurdabakan I (2008) The Effects of Self and Peer-Assessment on Basic Communication Skills Achievement. *World of the Medical Education* 27: 27-39.
 44. Topping K (1998) Peer Assessment Between Students in Colleges and Universities. *Review of Educational Research* 68: 249-276. Link: <http://bit.ly/34F8eTt>
 45. Woods NN (2007) Science is fundamental: the role of biomedical knowledge in clinical reasoning. *Med Educ* 41: 1173–1177. Link: <http://bit.ly/2Z7NWKi>
 46. Chang HJ, Kang J, Ham BJ, Lee YM. (2016). A functional neuroimaging study of the clinical reasoning of medical students. *Adv in Health Sci Educ*, 21: 969–982. <https://bit.ly/2xAFTTQ>
 47. Eroğlu L, Uresin Y (2003) A model of pharmacology education: the experience of Istanbul Medical Faculty. *J Clin Pharmacol* 43: 237-242. Link: <http://bit.ly/2sHxFXj>
 48. Rectorate Affiliated Centers of İstanbul University. Link: <http://bit.ly/2Q577r6>
 49. Research Project for Graduate Student. Scientific Research Project Coordination Unit of İstanbul University and The Scientific and Technological Research Council of Turkey. Link: <http://bit.ly/34GoZr8>
 50. European Union, Jean Monnet Erasmus+ Programme. <https://bit.ly/35H9qYH>
 51. Dornan T, Conn R, Monaghan H, Kearney G, Gillespie H, et al. (2019) Experience Based Learning (ExBL): Clinical teaching for the twenty-first century. *Med Teach* 41: 1098-1105. Link: <http://bit.ly/35lpc4C>

Dr. Meral Demir, MSc, PhD

Department of Medical Pharmacology and Clinical Pharmacology,
Istanbul Faculty of Medicine, Istanbul University, Millet Street, Fatih,
Capa 34093, Istanbul, Turkey, Fax: +902124142052;
E-mail: meral.demir@istanbul.edu.tr, meraleecn13@gmail.com

Published: 23-12-2019 | ISBN: 978-81-943057-5-0