

3. EARLY PHASE CLINICAL TRIALS SYMPOSIUM



TUCRIN

18-19 November 2021

18 Nov 2021, Thursday

15:00-15:15 WELCOME AND INTRODUCTION

Speaker: Fatih DEMİRKAN
(Dokuz Eylül University, Phase 1 Clinical Trial Center Coordinator, Izmir, Turkey)

Speaker: Yeşim TUNÇOK
(Director of TUCRIN, Izmir, Turkey)

15:15-16:15 EXEMPLARY TRIAL UNITS I

Chair: Irfan ÇİÇİN
(Trakya University School of Medicine, Division of Medical Oncology, Edirne, Turkey)

Chair: Necati GÖKMEN
(Dokuz Eylül University School of Medicine, Department of Anesthesiology, Reanimation and Intensive Care, Izmir, Turkey)

15:15- 15:45 Abbvie Clinical Research Units

Speaker: Sabriye DURAN
(Clinical Operations Country Manager, Abbvie Pharmaceutical, Istanbul, Turkey)

15:45-16:15 Pfizer Clinical Research Units (PCRU), Outstanding Example of in-House Phase-1 Clinical Research Sites

Speaker: Anna COLZI
(Vice President, Head of Pfizer Clinical Research Units, Brussels, Belgium/ New Haven, CT, USA)

16:15-17:15 EXEMPLARY TRIAL UNITS 2

Chair: Hayri ÖZSAN
(Dokuz Eylül University School of Medicine, Division of Hematology, Izmir, Turkey)

Chair: İnci ALACACIOĞLU
(Dokuz Eylül University School of Medicine, Division of Hematology, Izmir, Turkey)

16:15-16:45 Parexel London Early Phase Trial Unit

Speaker: Şebnem YILDIRIM
(Parexel, Early Phase Clinical Unit, Medical Director, London, UK)

16:45-17:15 IQVIA Center of Excellence Concept

Speaker: Şeniz SAĞOL
(IQVIA, Vice President of Clinical Operations, Istanbul, Turkey)

17:15-17:45 BREAK

17:45-19:15 FUTURE OF EARLY PHASE CLINICAL TRIALS IN TURKEY AND DIFFICULTIES ENCOUNTERED (HEALTH AUTHORITY, CONTRACT RESEARCH ORGANIZATION (CRO), PHARMACEUTICAL INDUSTRY AND RESEARCHERS' PERSPECTIVE)

Chair: Fatih DEMİRKAN
(Dokuz Eylül University, Phase 1 Clinical Trial Center Coordinator, Izmir, Turkey)

Chair: Mete HÜSEMOĞLU
(President, Association of Research-Based Pharmaceutical Companies, Istanbul, Turkey)

17:45-18:00 Nadir ULU
(R&D and Production, Deputy General Manager, Gen Pharmaceuticals, Ankara, Turkey)

18:00-18:15 Oğuz AKBAŞ
(General Manager, Monitor CRO, Istanbul, Turkey)

18:15-18:30 Nihan BURUL BOZKURT
(Association of Research-Based Pharmaceutical Companies, Health Policy Director, Ankara, Turkey)

18:30-18:45 Batuhan YEŞİLYURT
(Head of Project Management Support Department, Health Institutes of Turkey, Ankara, Turkey (TÜSEB))

18:45-19:00 Fatih DEMİRKAN
(Dokuz Eylül University, Phase 1 Clinical Trial Center Coordinator, Izmir, Turkey)

19:00-19:15 Discussion

19:15-19:45 CLINICAL RESEARCH IN HEMATOLOGICAL MALIGNITIES

Chair: Hamdi AKAN
(Chairman, Clinical Research Association, Ankara, Turkey)

19:15-19:45 Clinical Research in Hematological Malignities

Speaker: Nahla HASABOU
(Senior Medical Director in Oncology Medical Science, Astellas Pharmaceutical, Northbrook, Illinois, USA)

19:45 Assessment of The Day and Closure

19 Nov 2021, Friday

14:45-15:00 OPENING OF THE 2ND DAY

Speaker: Fatih DEMİRKAN
(Dokuz Eylül University, Phase 1 Clinical Trial Center Coordinator, Izmir, Turkey)

Speaker: Yeşim TUNÇOK
(Director of TUCRIN, Izmir, Turkey)

15:00-15:30 PHASE I CLINICAL TRIALS-1

Chair: Yeşim TUNÇOK
(Director of TUCRIN, Izmir, Turkey)

15:00-15:30 Designing Early Phase Trials: Challenges and Points to Consider from Planning to Execution

Speaker: Arzu GRANBERG
(Novartis Institutes for Biomedical Research, Translational Medicine Expert, Medical Director Neuroscience, Basel, Switzerland)

15:30-16:30 PHASE I CLINICAL TRIALS-2

Chair: Muzaffer DEMİR
(Trakya University School of Medicine, Division of Hematology, Edirne, Turkey)

Chair: Binnaz DEMİRKAN
(Dokuz Eylül University School of Medicine, Division of Oncology, Izmir, Turkey)

15:30-16:00 Adaptive Designs in Clinical Trials

Speaker: Semra YÖRÜK
(Sanofi Pharmaceutical, Clinical Research Oncology Development Director, Istanbul, Turkey)

16:00-16:30 Expectations of Sponsors from Phase 1 Trials Centers

Speaker: Alina CODRESCU
(BMS Pharmaceutical, Deputy Regional Clinical Operations Director, Romania and Turkey)

16:30-17:00 STATISTICS IN CLINICAL STUDIES

Chair: Yahya BÜYÜKAŞIK
(Hacettepe University School of Medicine, Division of Hematology, Ankara, Turkey)

16:30-17:00 Early Clinical Trials with Adaptive Design with Examples; Statistical Perspective

Speaker: Ömür Gökmen SEVİNDİK
(Medipol University, Division of Hematology, Istanbul, Turkey)

17:00-17:15 BREAK

17:15-18:15 WHAT SHOULD BE DONE TO DEVELOP NEW DRUGS PER PATIENT FROM THE LABORATORY IN TURKEY? WHAT ARE THE STRATEGIES TO FOLLOW?

Moderator: Derya UNUTMAZ
(Jackson Laboratories Connecticut, ABD)

Ahmet YOZGATLIGİL
(Vice President, The Scientific and Technological Research Council of Turkey, Ankara, Turkey)

Figen ÇİZMECİ ŞENEL
(Deputy Secretary General of TÜSEB, Ankara, Turkey)

Elif İnci ERGÖNÜL
(Head of Clinical Research Department, Turkish Pharmaceuticals and Medical Devices Agency, Ankara, Turkey)

Mete HÜSEMOĞLU
(President, Association of Research-Based Pharmaceutical Companies, Istanbul, Turkey)

Vedat EĞİLMEZ
(Pharmaceutical Manufacturers Association of Turkey, Istanbul, Turkey)

Fatih DEMİRKAN
(Dokuz Eylül University, Phase 1 Clinical Trial Center Coordinator, Izmir, Turkey)

18:15-18:45 INVESTIGATOR INITIATED CLINICAL TRIALS

Chair: Mustafa ÇETİNER
(Acibadem Hospital, Division of Hematology, Istanbul, Turkey)

18:15-18:35 The role of Investigator Initiated Studies in Clinical Research

Speaker: Julie RYU
(Director, Medical Affairs Research, Gilead Pharmaceutical, San Francisco California /USA)

18:35-18:45 Discussion

18:45 Adjourn