IST MEETING OF CLINICAL RESEARCH CLINICAL TRIAL

INTERNATIONAL DAY

UNIVERSITY OF PORTO RECTORY MAY 19, 2022



09:00 - 09:30 Reception and Accreditation

09:30 - 09:50 Opening Session

Elvira Fortunato | Minister of Science, Technology and Higher Education (TBC)

Catarina Resende Oliveira | President of Agency for Clinical Research and Biomedical Innovation • AICIB

António Sousa Pereira | Dean of the University of Porto

SESSION 1 | The Future of Clinical Research: European Strategy to accelerate the clinical research

09:50 - 11:10 Session chair: Helena Beaumont | AICIB

• Clinical Trials with Investigational Medicinal Products

Joel Passarinho | Clinical Trials Unit, Medicines Evaluation Directorate • INFARMED, I.P.

Clinical Investigation with Medical Devices

Lília Louzeiro | Health Products Directorate · INFARMED, I.P.

Challenges of the new clinical trial designs

Jacques Demotes | The European Clinical Research Infrastructure Network • ECRIN

· Ethical challenges of new clinical research modalities

António Lourenço | Portuguese Ethics Committee for Clinical Research \cdot CEIC

Discussion

11:10 - 11:30 **COFFEE BREAK**

SESSION 2 | How to build a successful path for the clinical research in Portugal

11:30 - 12:45 Session chair: Fernando Araújo | University Hospital Center of São João

• The importance of developing a clinical research organizational culture in the healthcare setting Teresa Machado Luciano | AICIB

International Examples

· Clinical Research at Hospital Level

Antonio Portolez | IdISSC, Hospital Clínico San Carlos, Madrid

· Clinical Research in Primary Health Care

Dionne Kringos-Pereira Martins | Amsterdam Public Health Research Institute and Amsterdam UMC

Discussion

12:45 - 14:00 LUNCH

ORGANIZING COMMITTEE













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14:00 - 16:00

Opportunities and initiatives at European level to develop the National clinical research

Session Chair: Anabela Isidro | AICIB

- FINANCING FUNDING Roadmap for Horizon Europe proposal preparation and submission hands on (NCPs) Afonso Duarte | AICIB
- RESEARCH INFRASTRUCTURES Support of research infrastrutures on funding application and trial management

Joana Batuca | ECRIN, PtCRIN

• EXAMPLE OF A PAN-EUROPEAN PLATFORM - Coordination and conduct of COVID-19 vaccine trials (VACCELERATE)

Laura Marques | Porto University Hospital Center

Conduct of Clinical Trials in a Health Institution

Session Chair: Heitor Costa | APIFARMA

• PUBLIC HOSPITAL PERSPECTIVE

João Massano | University Hospital Center of São João

• PRIVATE HOSPITAL PERSPECTIVE

Bárbara Parente | CUF Porto, Academic Center

CRO PERSPECTIVE

Luis Almeida | BlueClinical

DATA CENTER PERSPECTIVE

Carlos Domingos | Association for Innovation and Biomedical Research on Light and Image · AIBILI

• PHARMACEUTICAL INDUSTRY SPONSOR PERSPECTIVE

Elsa Branco | Clinical Research Working Group · APIFARMA

WK3 | **CTR-CTIS: DEMO**

Session Chair: Joel Passarinho | INFARMED, I.P.

• INTERACTIVE EXERCISE OF DEMONSTRATION - Submission of a Clinical Trial Application (CTA) to the Clinical Trials Information System (CTIS) in the scope of the EU Regulation N° 536/2014

ORGANIZING COMMITTEE













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Engagement and participation of the citizen/patient in clinical trials

Session chair: Elsa Frazão Mateus | President of EUPATI Portugal

CLINICAL TRIALS: THE PATIENT PERSPECTIVE

Ana Vieira | Portuguese League against Rheumatic Diseases, Sjögren Europe, EULAR

• INVOLVEMENT OF PEOPLE REPRESENTATIVES WITH DISEASE IN THE R&D PROCESS

Vítor Neves | Europacolon Portugal

Isabel Barbosa | Portuguese Association of Leukemias and Lymphomas • PALL

16:00 - 16:20 COFFEE BREAK

16:20 - 16:45 Workshops Conclusions and Take Home Messages Sessions chairs

SESSION 3 | Strategies for the advancement of the Clinical Research in Portugal

16:45 - 17:45 Session chair: Catarina Resende Oliveira | Agency for Clinical Research and Biomedical Innovation • AlCIB Rui Santos Ivo | National Authority of Medicines and Health Products • INFARMED Vitor Herdeiro | Central Administration of the National Health System • ACSS João Almeida Lopes | Portuguese Pharmaceutical Industry Association • APIFARMA Elsa Frazão Mateus | European Patients' Academy on Therapeutic Innovation • EUPATI Emília Monteiro | Portuguese Clinical Research Infrastructure Network • PtCRIN

17:45 Closing Session

António Sales | Deputy Minister for Health

VENUE



REITORIA DA UNIVERSIDADE DO PORTO

Praça Gomes Teixeira 4099-002 Porto Portugal ORGANIZING COMMITTEE

AICIB | Agency for Clinical Research and Biomedical Innovation

INFARMED. I.P. | National Authority of Medicines and Health Products

EUPATI-Portugal | The European Patients' Academy-Portugal

PtCRIN | Portuguese Clinical Research Infrastructure Network

APIFARMA | Portuguese Pharmaceutical Industry Association

U.PORTO | Porto University