

1ST MEETING OF CLINICAL RESEARCH CLINICAL TRIAL INTERNATIONAL DAY

UNIVERSITY OF PORTO RECTORY
MAY 19, 2022

SCHEDULE

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 • 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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WORKSHOPS | PARALLEL SESSIONS

14:00 - 16:00

WK1 | 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 infrastructures 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

WK2 | 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

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WK4 | 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

[Vitor 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 · AICIB

[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

U.PORTO

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