























**ENG 1/5** 



## OCTOBER 9, 2025 | CROWNE PLAZA BUCHAREST

# **AGENDA**

## **Registration & Welcome Coffee**

08:45 - 09:15

09:15 - 09:30

**Opening Remarks** 

**Acad. Prof. Dr. Victor Voicu,** Co-founder and Honorary President of SRCCC|RSCRC

09:30 - 09:45

**Keynote Speech** 

Prof. Daniel David, PhD, Romanian Minister of Research and Education, Co-founder & Member of the SRCCC | RSCRC Board

09:45 - 10:00

**Keynote Speech** 

**Prof. Dr. Adrian Streinu-Cercel**, President of the Health Committee of the Romanian Senate

Event organized by



Event MC: Ada Roseti





#### 10:00 - 11:30

# Competitive Advantage of Nations - Romania's Clinical Research Capabilities in 2025

The sustainable development of Romania's clinical research sector cannot rely solely on attracting international trials - it must also be built on the structured academic training of a new generation of well-prepared professionals. Despite the formal adoption of the EU Clinical Trials Regulation (EU CTR), local interpretation variances still persist, reflecting broader gaps in institutional alignment and capacity.

One of the most overlooked dimensions is the lack of consistent governmental investment in building human capital for this field. According to Michael E. Porter's theory of the Competitive Advantage of Nations, countries that invest in education, standards, and infrastructure create the conditions for long-term strategic positioning. A nationally recognized academic curriculum in clinical research - aligned with EU norms and including ECTS credits - would represent more than a technical upgrade: it would be a signal of strategic intent.

This panel will explore the role of academic training in shaping a qualified and competitive research environment in Romania, and how universities, regulators, and research stakeholders can jointly drive this transformation.

#### **Moderator:**

**Dr. Nic Voiculescu, EMBA,** Co-founder & President of the SRCCC|RSCRC Board *Membri în panel*:

**Prof. Daniel David, PhD,** Romanian Minister of Research and Education, Co-founder & Member of the SRCCC|RSCRC Board

**Prof. Dr. Patriciu Achimaș-Cadariu,** Coordinator of the R&D Dept. at "Prof. Dr. Ion Chiricuţă" Oncology Institute in Cluj-Napoca, Co-founder of SRCCC|RSCRC

**Dr. Hans Christian Hoeck,** CEO & President of Trialcare, Member of SCRS Leadership Council, Co-founder & Member of the SRCCC | RSCRC Board

**Prof. Dr. Viorel Jinga,** Rector of "Carol Davila" University of Medicine and Pharmacy in Bucharest, Co-founder of SRCCC|RSCRC

**Prof. Dr. Adrian Streinu-Cercel,** Senator, President of the Health Committee of the Romanian Senate

Prof. Ovidiu Dîmbean-Creta, PhD, Rector ASEBUSS

Dr. Tomasz Mackiewicz, Clinical Operations Lead for Roche Poland

**Coffee Break** 

11:30 - 11:45







#### 11:45 - 13:15

# Is Romania an Equal Opportunity Market for Clinical Research Operators?

Romania continues to demonstrate significant potential in the field of clinical research, with a strong foundation in medical expertise and growing engagement from global sponsors. Yet, its ability to truly compete in the international arena depends on how effectively it can address internal systemic inconsistencies and ensure a regulatory and financial environment that inspires trust, efficiency, and predictability.

In an increasingly competitive European landscape, where policy coherence and fair business practices are key differentiators, Romania (Authorities, Pharma industry, Clinical Research players/stakeholders, etc.) must re-evaluate certain fiscal and contractual mechanisms that may be unintentionally disadvantaging research centers or limiting investment. Disparities in how identical activities are interpreted / treated - financially or administratively - can weaken the country's strategic positioning.

This panel brings together representatives from financial and regulatory authorities alongside clinical research stakeholders, to reflect on Romania's current trajectory and explore solutions for building a more transparent, equitable, and competitive framework for the development of clinical trials.

#### Moderator:

Francisc Proinov, MD, MBA, Executive Director of SRCCC|RSCRC

#### Membri în panel:

**Dr. Bogdan Chiritoiu**, President of the Romanian Competition Council

**Conf. Dr. Cristian Celea,** Vice-president of the Romanian National Health Insurance House **Adina Vizoli,** Partner PwC România

**Alexandra Smedoiu, CFA,** Partner Deloitte on fiscality and Vice-President of CFA Romania **Răzvan Predica,** Chief Comercial Officer of Affidea | MedEuropa and Cluster CEO Romania Greece and Hungary

**Cătălin Radu,** General Manager Bristol Myers Squibb in Romania **Lucian Bozian,** Partner D&B David and Baias

ı	П	n	c	h	B	re	a	k

13:15 - 14:00







#### 14:00 - 15:30

# Digitalization & Artificial Intelligence in Clinical Research: from Electronic Data Capture to Informed and Patient-Centered Decisions

Digital transformation in clinical research is no longer a trend - it is a present reality. Electronic Data Capture (EDC) systems enable faster, more accurate, and secure data collection, while Artificial Intelligence (AI) opens new opportunities for predictive analytics and real-time decision-making. At the same time, tools such as Electronic Informed Consent Form (eICF) enhance the clarity, accessibility, and traceability of the informed consent process, improving patient understanding and engagement.

In parallel, the use of electronic Patient-Reported Outcome (ePRO) tools offers a direct, continuous perspective on the patient experience, contributing to more patient-centered research.

This panel will explore how these digital tools can be responsibly, efficiently, and ethically integrated into clinical trials involving human subjects - and will also address current barriers in Romania, from IT infrastructure and regulatory clarity to trust and adoption among patients and healthcare professionals.

#### **Moderator:**

**Dr. Francisc Proinov, MBA,** Executive Director of SRCCC|RSCRC

#### Membri în panel:

Raymond Nomizu, CEO & founder of CRIO

**Sarah Sutherland,** Associate Director, Regional Operational Delivery | UK and Ireland, PPD Clinical Research Services, part of Thermo Fisher Scientific

Andrei Ionut Damian, PhD, Founder of Ratio1.ai

**Alexandru Lazăr,** CEO and co-founder of docviser

**Dr. Hans Christian Hoeck, PhD,** CEO & President of Trialcare, Member of SCRS Leadership Council, Co-founder & Member of the SRCCC | RSCRC Board

**Obinna Onwude, BDS, MSc,** Principal - Strategic Consulting, Patient Centered Solutions IQVIA

**Coffee Break** 

15:30 - 15:45





#### 15:45 - 17:00

### General Public's and Healthcare Professionals' Perception on Clinical Research Activities

In Romania, clinical research activities remain relatively unknown to the general public and are often met with skepticism, despite its essential role in advancing medicine and providing early access to innovative therapies. This panel aims to bring forward the voices of patients, their families, as well as the perspectives of investigators, ethics committees, and patient organizations, to openly discuss what participation in a clinical trial truly means from ethical, emotional, and informational standpoints.

We will explore how patients' rights and informed consent are understood, and how communication and trust in clinical research can be promoted and strengthened.

The discussion will focus on identifying practical tools to improve transparency, education, promotion of clinical research/clinical trials and the active involvement of patients in clinical trial decision-making processes.

#### *Moderator:*

**Dr. Oana Cuzino, PhD,** Founder of DOC.ro - an online platform specialized in scientifically supported medical articles and digital recruitment for clinical research participants

#### Membri în panel:

**Rozalina Lăpădatu,** President of APAA (Asociația Pacienților cu Afecțiuni Autoimune), Vice-President of Alianța Pacienților Cronici din România, Co-founder of SRCCC|RSCRC

Andreea Damian, PhD, PHD in Communication for Public Health

- **Prof. Dr. Victor Strâmbu,** Vicepresident of CNBMDM (Comisia Naţională de Bioetică a Medicamentului şi a Dispozitivelor Medicale | The Romanian National Committee of Bioethics for Medical Treatments and Devices)
- **Prof. Dr. Dragoş Vinereanu,** President of the University Senate of "Carol Davila" University of Medicine and Pharmacy in Bucharest, Co-founder and Vice-president of the SRCCC | RSCRC Board
- **Răzvan Predica,** Chief Comercial Officer of Affidea | MedEuropa and Cluster CEO Romania Greece and Hungary
- **Psih. Răzvan Predatu, PhD,** Prodean of the Faculty of Psychology and Science of Education at The Babeș-Bolyai University in Cluj-Napoca

17:00 - 17:10

# **Closing Remarks**

Dr. Nic Voiculescu, EMBA, Co-founder & President of the SRCCC | RSCRC Board