

ICTD INTERNATIONAL CLINICAL
TRIALS DAY
20 MAY 2019

**PATIENT
STRATIFICATION
STUDIES**



Paris, Luxembourg Palace

International Clinical Trials Day (ICTD) 2019

**Patient Stratification Studies:
Challenges and Opportunities**

*Paris, Luxembourg Palace,
15 rue de Vaugirard, 75006 Paris, room Clemenceau
20 May 2019*

Introduction

Every year since 2005, ECRIN (whose mission is to support multinational clinical research in Europe) celebrates International Clinical Trials Day (ICTD) on May 20th, the anniversary of the first-ever clinical trial, led by James Lind in 1747 on sailors with scurvy. ICTD is an opportunity to discuss – with health policy actors, health authorities, researchers, health professionals, patients and citizens – the issues and challenges of clinical research, and in particular patient-centred research.

Patient-centred research aims to answer the question ‘what is the best therapeutic solution for a given condition?’ In recent years, it has become possible to produce big data for each patient, (through genomics, transcriptomics, proteomics, metabolomics, imaging, etc.), and then to analyse data via algorithms proposing a stratification into homogeneous subgroups. These developments make it possible to ask a new question, more in line with the objectives of personalised medicine: ‘what is the best therapeutic solution for this subgroup of patients?’

Stratification programmes raise a number of important issues which will be addressed during the conference; they concern methodology, data and sample transfer, consent and protection of personal data, data and image processing, and use of stratification algorithms. Stratification programmes also raise questions related to research and health policy for funders, regulators, and health authorities.

This year, ICTD is being celebrated in France, in partnership with F-CRIN (French Clinical Research Infrastructure Network), ECRIN’s French partner. Based on a use case, the conference aims to address the main challenges and opportunities raised by patient stratification programmes.

Jacques Demotes
Director General ECRIN

Olivier Rascol
Coordinator F-CRIN

AGENDA 1/2

Time:	Description:	Who:
10:00 – 10:30	Coffee/registration	
10:30 – 11:00	Opening session	Gilles Bloch, CEO of INSERM Jacques Demotes, director general, ECRIN Olivier Rascol, coordinator, F-CRIN
Part I: Technical and methodological issues related to patient stratification studies		
11:00 – 11:25	The 'AETIONOMY' study ¹	Jean-Christophe Corvol, professor of neurology (ICM, Pitié-Salpêtrière Hospital, APHP, Inserm, Sorbonne Université) (Paris, France)
11:25 – 11:50	Design and statistical methodology in patient stratification programmes: stratification cohort, validation cohort, clinical trials	Raphaël Porcher, associate professor of biostatistics at Paris Descartes University (Paris, France)
11:50 – 12:15	Multimodal data management: clinical, multi-omics and imaging data	Jan-Willem Boiten, programme manager at Lygature (Utrecht, Netherlands)
12:15 – 12:40	Multinational cohort integration	Josep Maria Haro, research and innovation director of <i>Fundació Sant Joan de Déu</i> (Barcelona, Spain)
12:40 – 12:50	Welcoming remarks	Gérard Larcher, President of the Senate
12:50 – 13:10	Panel discussion	Chair: Jacques Demotes, director general, ECRIN (Paris, France)
13:10 – 14:10	Lunch	
14:10 – 14:35	Machine learning algorithms for patient stratification	David Sadek, vice president for Research, Technology & Innovation, Thales (Paris, France)

¹ Full study title: Taxonomy of Neurodegenerative Diseases: Observational Study in Alzheimer's Disease and Parkinson's Disease. AETIONOMY has received funding from the Innovative Medicines Initiative (IMI) under grant agreement number 115568. Website: www.aetionomy.eu

AGENDA 2/2

Time:	Description:	Who:
Part II: Science policy aspects of personalised medicine		
14:35 – 15:00	Reuse of data and biosamples, informed consent and personal data protection challenges	Michaela Th. Mayrhofer, chief policy officer, head of CS ELSI, BBMRI-ERIC (Graz, Austria)
15:00 – 15:25	Promoting international cooperation in personalised medicine research: International Consortium for Personalised Medicine (ICPerMed)	Astrid Vicente, senior researcher, head of the Department of Health Promotion and Non-communicable Disease Prevention, <i>Instituto Nacional de Saúde Doutor Ricardo Jorge</i> (Lisbon, Portugal); ICPerMed vice-chair
15:25 – 15:50	The challenges of patient stratification studies and personalised treatments for health technology assessment	Frank Hulstaert, senior researcher, Belgian Health Care Knowledge Centre (KCE) (Brussels, Belgium)
15:50 – 16:15	Panel discussion	Chair: Olivier Rascol, coordinator, F-CRIN (Toulouse, France)