ICTD INTERNATIONAL CLINICAL TRIALS DAY 20 MAY 2019

PATIENT STRATIFICATION STUDIES

ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Paris, Luxembourg Palace

International Clinical Trials Day 2019:
Patient stratification studies: challenges and opportunities
Paris, Luxembourg Palace, 20 May 2019

Every year since 2015, 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 will be celebrated in France, in partnership with F-CRIN (French Clinical Research Infrastructure Network), ECRIN's French partner, in the premises of the Luxembourg Palace on Monday, May 20th, 2019. Based on a use case, the conference will address the main challenges and opportunities raised by patient stratification programmes.

Jacques Demotes
Director General ECRIN

Olivier Rascol
Coordinator F-CRIN

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DRAFT AGENDA

Time:	Description:	Who:
10:00 – 10:30	Coffee/registration	
10:30 – 11:00	Opening session	Mr Gérard Larcher, President of the Senate Mrs Frédérique Vidal, Minister of Higher Education, Research and Innovation Mr Gilles Bloch, CEO of INSERM
Part I: Technical and methodological issues related to patient stratification studies		
11:00 – 11:25	The 'AETIONOMY' study[1]	Jean-Christophe Corvol, director of the Clinical Investigations Centre (CIC) of the Brain & Spine Institute (ICM) at Pitié-Salpêtrière Hospital (Paris, France)
11:25 – 11:50	Design and statistical methodology in patient stratification programmes: stratification cohort, validation cohort, clinical trials	Rafaël 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	Machine learning algorithms for patient stratification	TBD
12:40 – 13:00	Panel discussion	Chair: Jacques Demotes, director general, ECRIN (Paris, France)
13:00 – 14:00	Lunch	

[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

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Time:	Description:	Who:
Part II: Technical and methodological issues related to patient stratification studies		
14:00 – 14:25	Multinational cohort integration	Josep Maria Haro, research and teaching director of Fundació Sant Joan de Déu (Barcelona, Spain)
14:25 – 14:50	Reuse of data and biosamples, informed consent and personal data protection challenges	Michaela Mayrhofer, senior project manager, BBMRI-ERIC (Graz, Austria)
14:50 – 15:15	Promoting international cooperation in personalised medicine research: International Consortium for Personalised Medicine (ICPerMed)	Astrid Vincente, head of the Department of Health Promotion and Non-communication Disease Prevention, principal investigator (Lisbon, Portugal)
15:15 – 15:40	Therapeutic indication based on a multi-omics signature? A regulatory challenge for marketing authorisation	TBD
15:40 – 16:05	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)
16:05 – 16:30	Panel discussion	Chair: Olivier Rascol, coordinator, F-CRIN (Toulouse, France)

Participation is free and on a first-come, first-served basis. The deadline for registration is 3 May 2019 (or earlier if the maximum number of participants is reached). Event location: Luxembourg Palace, 15 rue de Vaugirard, 75006 Paris, room Clemenceau.

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fcrin French Clinical Research Infrastructure Network

Paris, Luxembourg Palace

About ECRIN

The European Clinical Research Infrastructure Network (ECRIN) is a sustainable, non-profit, distributed infrastructure with the legal status of a European Research Infrastructure Consortium (ERIC).
ECRIN supports multinational clinical trials in Europe, providing increased access to patients, resources and expertise. In particular, ECRIN supports investigators and sponsors in the preparation of trial protocols and funding applications, and can subsequently provide services for the management of multinational trials. ECRIN is also involved in activities to enhance the ability of European institutions to successfully conduct multi-country clinical research (e.g. tools/database development, data centre certification). Moreover, ECRIN is involved in infrastructure development projects that aim to further develop the European clinical research community and facilitate multinational trials.

ECRIN
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www.ecrin.org | @ECRIN_ERIC

About F-CRIN

The French Clinical Research Infrastructure Network (F-CRIN), created in 2012, unites the major academic and commercial stakeholders in clinical research in France, including clinical research and innovation departments in university hospitals, clinical investigation centres, and interregional groups for clinical research and innovation.
F-CRIN enables multinational or multicentre, investigator-driven, clinical trials and early phase proof-of-concept studies. Clinical trial support is provided through F-CRIN by the EUCLID and PARTNERS platforms of professional services. F-CRIN also collaborates with networks specialised in specific diseases or areas of medicine (e.g. cardiology, nutrition, inflammatory disease, cardiorenal diseases, thrombosis, vaccinology, Parkinson's disease, sepsis).
F-CRIN recently labelled five new investigational networks for paediatrics, diseases of the retina, severe asthma, multiple sclerosis, and research in clinical epidemiology and public health.
F-CRIN is the single contact point facilitating the participation of France in ECRIN-supported multinational clinical studies.

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