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

Press Release – Paris, April 2019. The European Clinical Research Infrastructure Network (ECRIN) and its French scientific partner, the French Clinical Research Infrastructure Network (F-CRIN), are organising a conference in Paris, France on May 20th, 2019 to celebrate International Clinical Trials Day (ICTD). The theme of this year's ICTD celebration is 'Patient stratification studies: challenges and opportunities'.

ICTD 2019 will bring together ECRIN's and F-CRIN's internal stakeholders and partners, and additional scientists and policymakers from France, the rest of Europe, and beyond. The meeting objective is to engage participants in discussion on the issues and challenges of clinical research, and in particular patient-centred research in the (academic) European clinical research context.

The meeting will take place at Luxembourg Palace from 10:30 to 16:30 CET. 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). Registration is mandatory via this link: bit.ly/2uOooux

'Recent developments in clinical research, and in particular in big data (through genomics, transcriptomics, proteomics, metabolomics, imaging, and more), present new opportunities for patient-centred research / personalised medicine,' said Jacques Demotes, director general of ECRIN. 'Yet, stratification raises a number of important issues for researchers, funders, regulators and health authorities, many of which we hope to address during the conference. These include methodology, data and sample transfer, consent and protection of personal data, data and image processing, use of stratification algorithms, and more'.

Opening comments will be made by Gérard Larcher, president of the French Senate, Gilles Bloch, CEO of the French National Institute of Health and Medical Research (*Institut national de la santé et de la recherche médicale,* INSERM), and professors Jacques Demotes and Olivier Rascol (coordinator of F-CRIN). The conference will then feature a talk about an ongoing patient stratification study entitled 'Taxonomy of Neurodegenerative Diseases: Observational Study in Alzheimer's Disease and Parkinson's Disease' ('AETIONOMY').[1] The investigator-led study, which is currently supported by ECRIN, will serve as a 'use case', illustrating the various issues and challenges that arise from a multinational clinical study using patient stratification. Subsequent talks will then address these issues and challenges, proposing paths forward to take advantage of the opportunities created by patient stratification and patient-centred research in the age of big data. The ultimate goal is to develop the best therapeutic solution for specific subgroups of patients. For the full draft agenda, see below.

'We are excited that so many leading scientific experts and influential leaders have agreed to speak at ICTD 2019. Their experience and scientific insight will allow for fruitful discussions on the many technical and methodological issues and science policy aspects related to patient stratification studies and personalised medicine in Europe,' commented Prof. Rascol.

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[1] The AETIONOMY study has received funding from the Innovative Medicines Initiative (IMI) under grant agreement number 115568. Website: www.aetionomy.eu

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Personalised medicine

Personalised medicine aims to deliver the best and most appropriate healthcare strategy to each patient subgroup. This requires the identification of patient groups based on the understanding of disease mechanisms (hypothesis-driven approach) or following mechanism-agnostic clustering (data-driven approach). Although both approaches can co-exist, the data-driven approach is now made easier because of the availability of large multimodal datasets combining clinical, imaging and multiomics data from broad patient populations, collected either prospectively or retrospectively in the context of observational or interventional studies. Such large datasets are exploited by machine-learning algorithms to stratify the patient population.
Regardless of the approach used to stratify patients, randomised clinical trials are necessary to compare and validate treatment strategies. Depending on the nature of the biomarker signature underpinning stratification, and the understanding of the drug's mechanism of action, linking a biomarker profile with a treatment option may be a relatively easy or very difficult task. New designs (i.e. basket and umbrella trials) are becoming more widespread in randomised trials in order to validate proposed treatment options. Although these approaches were first designed and implemented in the field of cancer, they have now spread rapidly to other disease areas.

Draft agenda

Opening session:

- Mr. Gérard Larcher, president of the Senate
- Mr. Gilles Bloch, CEO of INSERM
- Prof. Jacques Demotes, director general of ECRIN
- Prof. Olivier Rascol, coordinator of F-CRIN

Part I

- The 'AETIONOMY' study: Jean-Christophe Corvol, director of the Clinical Investigations Centre (CIC) of the Brain & Spine Institute (ICM) at Pitié Salpêtrière Hospital (Paris, France)
- 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)
- Multimodal data management: clinical, multi-omics and imaging data: Jan-Willem Boiten, programme manager at Lygature (Utrecht, Netherlands)
- Machine learning algorithms for patient stratification: David Sadek, vice president for Research, Technology & Innovation, Thales (Paris, France)
- Panel discussion

Part II

- Multinational cohort integration: Josep Maria Haro, research and teaching director of Fundació Sant Joan de Déu (Barcelona, Spain)
- Reuse of data and biosamples, informed consent and personal data protection challenges Michaela Mayrhofer, senior project manager, BBMRI-ERIC (Graz, Austria)
- 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, Instituto Nacional de Saúde Doutor Ricardo Jorge (Lisbon, Portugal); ICPerMed vice-chair Patient perspective on personalised medicine: TBD
- 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)
- Panel discussion

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About ICTD

ICTD was launched in 2005 to commemorate the day James Lind started his famous clinical trial on scurvy (May 20th, 1747) and laid the foundation for modern clinical research. Celebrated every year on or around May 20th, ICTD is an opportunity for organisations, clinical research professionals, and the public to acknowledge the achievements that result from clinical research and to discuss various trial topics. ECRIN hosts an annual celebration of ICTD, organised in collaboration with one of its national scientific partners.

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 has a national partner in each country, with F-CRIN being the partner for France.

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.

www.fcrin.org | @FCRIN_network

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