From Gene-Targeted Tests to Genome-Wide Data in Cancer Genetics: A Paradigm for the Development of Personalised Genomic Medicine?

Second workshop

Personalised Genomic Medicine and Therapeutic Innovation
The Case of Cancer

Amphithéâtre Marie Curie – Institut Curie
1, rue Pierre et Marie Curie
75005 Paris

February 6-7, 2014

Personalized genomic medicine mainly involves the implementation of targeted therapies in oncology, and especially drugs that block specific proteins involved in the tumoral process. Indeed, some drugs are now being marketed with their companion diagnostic test, that is, the test for the biomarker defining the patients or population for whom the drug is effective. Personalized medicine thus favors an extension of industry's role in new forms of treatment, by creating opportunities for developing tests and new drugs and for recycling old drugs in specific subpopulations and in novel indications and combinations. This can be done at a higher scale when next-generation sequencing is involved, also offering outlets for the machines needed to analyze diseased tissues and identify variants. The pharmaceutical industry has invested the field of personalized medicine as a promising response to the present crisis in drug innovation, in that it allows for input from clinical experience into the usual drug development pipelines. Industry will thus be a key player in the success or demise of personalized medicine.

Oncology is presently recognized as the field in which personalized genomic medicine began and has best taken hold. This is explained in part by the fact that analyzing and classifying tumors, with the aim of improving diagnosis, prognosis and treatment, is already a well-established practice in this specialty. Genomics now offers the possibility of identifying genetic alterations common to different types of tumors; this could become the basis of a new molecular taxonomy that refines oncology's approach to diagnosis and prognosis, and helps pinpoint the most effective or best tolerated treatment (or avoid ineffective treatment with toxic side effects). Oncology is also the specialty in which the peculiar culture of the clinical trial has become a routine practice: almost all patients are involved and treatment is set up

Workshop Coordinators:

Simone Bateman, *Senior Researcher, Sociology, CERMES3 (CNRS/University Paris Descartes/EHESS/INSERM)*

Dominique Stoppa-Lyonnet, *Professor of Medical Genetics, Head of the Genetics Department (Institut Curie/Hospital and University Paris Descartes)*

around, not one molecule, but a protocol, organized within a specific time frame and testing a combination of molecules known as a “chemotherapy regimen”. However, as cancer treatment is progressively customized to smaller groups of patients, the usual rules governing the conduct of clinical trials will tend to be challenged and to evolve.

The objective of this workshop is to explore cancer as a paradigmatic case study of personalized genomic medicine, identify the features that characterize this model, and discuss the validity of its extension to other types of disease.

PROGRAMME

Thursday February 6, 2013

9:00 Welcome Coffee

9:15 - 9:30 Introduction to the Second Workshop

Dominique Stoppa-Lyonnet and **Simone Bateman** (workshop coordinators)

9:30 – 10h45 An overview of Cancer Genomics

Pr. Michael Stratton, Director of the Wellcome Trust Sanger Institute and joint head of the Cancer Genome Project (U.K).

Discussion introduced by **Jean Gayon**

Coffee break

11:00 -13:00 New Clinical and Industrial Strategies in Cancer Research and Treatment

Chair: **Dominique Stoppa-Lyonnet,** Professor of Medical Genetics, Institut Curie, University Paris Descartes

Prof. Fabien Calvo, Joint Director and Director of Research, French National Cancer Institute (INCa):

Dr. Frédéric Eberlé, Roche Diagnostics France :
Cooperation as a Challenge for Pharmaceutical Companies, Diagnostic Companies and Academia in the Development of Personalized Medicine

Vincent Fert, Qiagen Marseille

General discussion introduced by: **Maurice Cassier**, Senior Researcher CNRS, Sociology, CERMES3 (CNRS/ /EHESS/University Paris Descartes/INSERM)

13h - Lunch

14:30 – 17:00 Cancer Genomics: a challenge for the design and practice of clinical trials?

14:30 – 15:45 The clinician's perspective

Christophe Le Tourneau, Oncology, Coordinator of the SHIVA clinical trial, SIRIC Research Programme, Institut Curie

Discussion introduced by: **Ilana Löwy,** Senior Researcher INSERM, History of Science, CERMES3 (INSERM/University Paris Descartes/EHESS/CNRS)

Coffee Break

16:00 – 17h15 The biostatistician's perspective

Donald A. Berry, Professor of Biostatistics, The University of Texas, M.D. Anderson Cancer Center (USA)

Discussion introduced by: **Catherine Bourgain**, Researcher INSERM, Genetic Epidemiology, CERMES3 (INSERM/University Paris Descartes/EHESS/CNRS)

Friday February 7, 2013

9h00 – 11h00 ***Challenges to Current Systems of Drug Regulation***

Chair: **Pierre Jouannet,** Emeritus Professor of Medicine, Reproductive Biology (University Paris Descartes), member of the French Academy of Medicine

Marisa Papaluca-Amati, European Medical Agency

Stuart Hogarth, Kings College London

General discussion introduced by: **Christian Bonah,** Professor of History of Science, Université de Strasbourg, SAGE (CNRS UMR7363)

Coffee break

11:15 – 12:15 Personalized Genomic Medicine and Therapeutic Innovation in Historical Perspective

Jean-Paul Gaudillière, Senior Researcher INSERM, Director of CERMES3 (INSERM/University Paris Descartes/EHESS/CNRS)

Final discussion chaired by Simone Bateman and *Dominique Stoppa-Lyonnet*

12h15 - 12-30 Concluding Remarks: Simone Bateman and **Dominique Stoppa-Lyonnet**