



ULB CERTIFICATE IN TRANSLATIONAL MEDICINE

Academic year 2015-2016



Institute for
Interdisciplinary
Innovation in healthcare

PROGRAM WEEK 1 : TRANSLATIONAL MEDICINE IN PERSPECTIVE

Coordinator: M. GOLDMAN

All lectures of the seminar will take place at
Auditoire EF2 303 - Campus Erasme, ULB



TRANSLATIONAL MEDICINE IN PERSPECTIVE

4 January 2016

MORNING SESSION : 9H-12H

- > Welcome : Marco SCHETGEN
- > Setting the scene : Michel GOLDMAN
- > Evidence-based medicine : Christian MELOT
- > Experimental medicine : Jean-Louis VINCENT

AFTERNOON SESSION : 14H-17H

- > Genomic medicine : Guillaume SMITS
- > How collaboration between Physicians and Engineers prepare the future of Medicine : Alain DELCHAMBRE & Jacques DEVIERE

THE HEALTHCARE LANDSCAPE

5 January 2016

MORNING SESSION : 9H-12H

- > Cost-effectiveness in healthcare : Alain DE WEVER
- > Basics of health economics : Mattias NEYT
- > Health-technology assessment : Frank HULSTAERT

AFTERNOON SESSION : 14H-17H

- > The multiple steps in drug innovation : Bruno FLAMION
- > The value chain in drug development : Edouard CROUFFER

PHARMACOTHERAPY AND OTHER HEALTH TECHNOLOGIES

6 January 2016

MORNING SESSION : 9H-12H

- > Pharmacotherapy : Michel GOLDMAN & Bruno FLAMION
- > Vaccines and prophylaxis against infectious diseases : Pierre SMEESTERS
- > Surgery and robotics : Didier DE CANNIÈRE

AFTERNOON SESSION : 14H-17H

- > Medical devices : Jacques GOLDSTEIN
- > Imaging technologies : Serge GOLDMAN

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EFFICACY AND SAFETY OF HEALTH TECHNOLOGIES

7 January 2016

MORNING SESSION : 9H-12H

- > Overview of regulatory approval processes : Greet MUSCH
- > Pharmacovigilance : Speaker to be nominated by AFMPS
- > Regulation of advanced therapy medicinal products :
Claire BEUNNEU

AFTERNOON SESSION : 14H-17H

- > The different stages in clinical development of medicines :
Michel TOUNGOUZ
- > The different stages in clinical development of medical
devices : Emmanuel BARTHOLOMÉ

THE GATEWAYS TO BUSINESS DEVELOPMENT IN HEALTHCARE

8 January 2016

MORNING SESSION : 9H-12H

- > The initial steps in value creation : from intellectual
property protection to technology transfer : Cécile GALLE
& Natalia KAPETANAKI (the patenting system)
- > From research to business : how to capture value - the new
business models in life sciences : Azèle MATHIEU
- > Strategies towards regulatory approval : Isabelle HUYS

AFTERNOON SESSION : 14H-17H

- > Public-private partnerships for drug innovation :
Hilde STEVENS & Magda PAPADAKI

PROGRAM WEEK 2 : BASICS OF PRECLINICAL RESEARCH

Coordinator: P. CHATELAIN

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THE PRE-CLINICAL PHASES IN BIOPHARMACEUTICAL R&D

11 January 2016

MORNING SESSION : 9H-12H

- > Introduction : Pierre CHATELAIN
- > Pre-clinical research : value and limits :
Jean-Paul PRIEELS
- > In vivo models of disease : Marcelle VAN MECHELEN
- > In vitro models of disease : Antoine BONDUE

AFTERNOON SESSION : 14H-17H

- > Pharmacokinetics and pharmacodynamics :
Jean-Marie NICOLAS
- > Use of human tissues for identification of candidate genes :
Décio EIZIRIK

DRUG TARGETS

12 January 2016

MORNING SESSION : 9H-12H

- > Identification and validation of drug targets :
Jean-Marie BOEYNAEMS, Pierre CHATELAIN,
Michel DETHIEUX

AFTERNOON SESSION : 14H-17H

- > Toxicology : Dimitri KOURETAS
- > Biopharmaceuticals : Eddy ROMMEL
- > Case study : Marc PARMENTIER

DRUG LIBRARIES

13 January 2016

MORNING SESSION : 9H-12H

- > Establishment of drug libraries : Yannick QUESNEL
- > High throughput screening : Pierre CHATELAIN

AFTERNOON SESSION : 14H-17H

- > Case study : Jean-Marie NICOLAS

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PROJECT MANAGEMENT, KNOWLEDGE MANAGEMENT AND RISK MANAGEMENT IN HEALTHCARE R&D

14 January 2016

MORNING SESSION : 9H-12H

- > Project management : Pierre CHATELAIN
- > Risk management : Emmanuel BARTHOLOMEÉ

AFTERNOON SESSION : 14H-17H

- > Experimental design in preclinical research :
Mariana IGUILLO-ESTEVE
- > Data collection, data analysis and statistics in preclinical
research : Mariana IGUILLO-ESTEVE

QUALITY AND COMMUNICATION OF RESEARCH RESULTS

15 January 2016

MORNING SESSION : 9H-12H

- > Quality in academic research : Michel TOUNGOUZ
- > Quality control in clinical biology : Anne KORNREICH
- > Quality from a regulatory stand-point : Alon FAUCONNIER

AFTERNOON SESSION : 14H-17H

- > Scientific communication and writing in life sciences :
Cécile GALLE
- > Master class on tips for publishing research results :
Décio EIZIRIK

PROGRAM WEEK 3 : BASICS OF CLINICAL RESEARCH

Coordinator: J.-L. VINCENT

All lectures of the seminar will take place at
Auditoire EF2 303 - Campus Erasme, ULB

SOCIETAL AND REGULATORY ASPECTS OF CLINICAL INVESTIGATIONS

18 January 2016

MORNING SESSION : 9H-12H

- > **Biomedical research : commercial vs. non-commercial trials** : Michel TOUNGOUZ & Bruno FLAMION
- **Bioethics and societal aspects** : Natalia KAPETANAKI

AFTERNOON SESSION : 14H-17H

- > **Overview of clinical trial legislation at EU and national level** : Greet MUSCH
- > **Regulatory requirements for authorizations of clinical trials** : Kristof BONNARENS
- > **Good clinical practice compliance from a regulatory standpoint** : Dominique DELFORGE

DESIGNING CLINICAL TRIALS

19 January 2016

MORNING SESSION : 9H-12H

- > **Patient selection and clinical endpoints** : Jean-Louis VINCENT
- > **Surrogate markers** : Emmanuel BARTHOLOMÉ
- > **Collaborative clinical trials : the EORTC model** : Françoise MEUNIER

AFTERNOON SESSION : 14H-17H

- > **Novel trial designs** : Christian MELOT
- > **Patient informed consent** : Patrick BISTON

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ELECTRONIC HEALTH RECORDS, MOBILE HEALTH TECHNOLOGIES, ROLE OF PATIENTS 20 January 2016

MORNING SESSION : 9H-12H

- > Electronical health records : Dipak KALRA
- > Mobile health technologies : Pascal COOREVITS
- > Critical Care : Jacques CRETEUR

AFTERNOON SESSION : 14H-17H

- > Global health : Lisa BONADONNA
- > The access of patients to innovative medicines : Marc TOMAS

CLINICAL INVESTIGATIONS IN CANCER AND RARE DISEASES 21 January 2016

MORNING SESSION : 9H-12H

- > Clinical trials in practice: EORTC as a model for cancer research : Sandrine MARREAUD
- > The role of the surgeon in clinical trials : Vincent DONCKIER
- > The role of patients in drug development : Laure SONNIER

AFTERNOON SESSION : 14H-17H

- Rare diseases in the development of new medicines
- > Repurposing of GLP-1 analogs: from diabetes to neurodegenerative diseases : Miriam CNOP
 - > Novel targeted therapies for hypereosinophilic disorders : Florence ROUFOSSE

SPECIAL PATIENT POPULATIONS AND BIOBANKS 22 January 2016

MORNING SESSION : 9H-12H

- > The child under trial : Georges CASIMIR
- > The elderly under trial : Thierry PEPERSACK
- > Big Data in Medicine : HUGHUES BERSINI

AFTERNOON SESSION : 14H-17H

- > Biobanks : Isabelle HUYS
- Data privacy and data protection : Isabelle HUYS & Guillaume SMITS

**PROGRAM WEEK 4 :
INTRODUCTION TO ENTREPRENEURSHIP
AND NEW CAREER PATHS**

Coordinator: O. WITMEUR

All lectures of the seminar will take place at
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**INTRODUCTION TO FUNDAMENTALS
OF HEALTHCARE ENTREPRENEURSHIP**

Olivier WITMEUR & HeeJung JUNG

25 January 2016

MORNING SESSION : 9H-12H

- > What entrepreneurship is and the entrepreneurship framework: People, Opportunity and Resources
- > Building a team and distinguishing role inside new ventures

AFTERNOON SESSION : 14H-17H

- > What makes a good idea? Market and industry attractiveness
- > Mapping the ecosystem. Who are the key stakeholders in the new venture creation process?

**FROM RESEARCH TO BUSINESS,
THE JOURNEY FROM IP TO COMPANY**

Florian TAÛBE & Jean NUWENBORG

26 January 2016

MORNING SESSION : 9H-12H

- > New venture incubation
- > The business plan

AFTERNOON SESSION : 14H-17H

- > Managing for growth: the life cycle of a new venture
- > Alliances and partnership negotiation

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**FUNDING HEALTHCARE VENTURES
FROM ALCHEMY TO IPO**

Olivier WITMEUR & Alain PARTHOENS
27 January 2016

MORNING SESSION : 9H-12H

- > The basics of venture capital
- > Grants, business angels and early stage venture capital (case study)

AFTERNOON SESSION : 14H-17H

- > Early development venture capital (case study)
- > Later stages venture capital and Initial Public Offering (case study)

**THE INNOVATION LEADER,
ENTREPRENEURSHIP BEYOND NEW
VENTURE CREATION**

John METSELAAR
28 January 2016

MORNING SESSION : 9H-12H

- > What innovation is/is not
- > Innovation culture

AFTERNOON SESSION : 14H-17H

- > Overview of innovation systems
- > The role of leadership

EVALUATION - DEBRIEFING

M. Goldman, JL Vincent, B. Flamion, P. Chatelain,
E. Bartholomé, C. Galle
29 January 2016

Emmanuel BARTHOLOME

Neurologist at CHU Tivoli, La Louvière, past-Medical Director at Medical Device Works

Georges CASIMIR

Vice-Doyen à l'Enseignement Faculté de Médecine ULB, Directeur Général Médical Hôpital Universitaire des Enfants Reine Fabiola

Hughues BERSINI

Professor in Université libre de Bruxelles and Co-Director of the IRIDIA laboratory

Pierre CHATELAIN

Previous Head of in vitro pharmacology, UCB

Claire BEUNEU

Non-clinical assessor, Federal agency for medicines and health products

Miriam CNOP

Associated Head of Clinic and Senior Research Fellow, Department of Endocrinology, Hôpital Erasme, and Center for Diabetes Research, ULB

Patrick BISTON

Chef de Service des Soins Intensifs, CHU Marie Curie

Jean-Marie BOEYNAEMS

Professor of pharmacology & Director of the Pharmed program, ULB

Pascal COOREVITS

Ghent University, The European Institute for Health Records

Lisa BONADONNA

Vice-President and Head of the Save the Children Partnership at GlaxoSmithKline (MSc degree in Public Health Policy, London School of Economics)

Jacques CRETEUR

MD Hôpital Universitaire Erasme, Chef de service Soins intensifs

Edouard CROUFER

Chairman of the Board, Croix-Rouge de Belgique & former Global R&D Head at UCB

Antoine BONDUE

Professor, Institut de recherche en Biologie humaine et moléculaire de l'ULB - IRIBHM

Didier DE CANNIÈRE

Professor of Surgery Hôpital Saint Pierre Brussels

Kristof BONNARENS

Head of clinical trials division, Federal Agency for Medicines and Health Products

Alain DELCHAMBRE

Professor, Ecole Polytechnique de Bruxelles

Dominique DELFORGE

GCP Inspector at AFMPS (Agence Fédérale des Médicaments et des Produits de Santé)

Michel DETHIEUX

CEO ITeos S.A

Jacques DEVIERE

Professor of Medicine, Head, Department of Gastroenterology, Hepatopancreatology and digestive Oncology, Director, Laboratory of Experimental Gastroenterology

Vincent DONCKIER

Chef de Clinique, Clinique de Transplantation Abdominale, Service de Chirurgie Digestive, Hôpital Erasme, ULB

Décio EIZIRIK

Director, ULB Center for Diabetes Research, ULB

Alain FAUCONNIER

Expert at AFMPS (Agence Fédérale des Médicaments et des Produits de Santé)

Bruno FLAMION

Professor of Pharmacology at University of Namur, expert for European and Belgian regulatory agencies

Cécile GALLE

MD, PhD with expertise in business development and scientific communication

Michel GOLDMAN

Founder of the Institute for Interdisciplinary Innovation in healthcare, ULB & former Executive Director of the Innovative Medicines Initiative

Serge GOLDMAN

Head of the Department of Nuclear Medicine, Hôpital Erasme, ULB

Jacques GOLDSTEIN

Clinical Outcome Director, Edwards LifeSciences

Frank HULSTAERT

Senior Researcher, Belgian Health Care Knowledge Centre

Isabelle HUYS

Professor, Department Pharmaceutical and Pharmacological Sciences Clinical Pharmacology and Pharmacotherapy

Mariana IGOLLO-ESTEVE

ULB Center for Diabetes Research

HeeJung JUNG

Assistant Professor of Entrepreneurship at Imperial College Business School, London (teaching entrepreneurship and business plan in the MSc International Health Management)

Dipak KALRA

President, The EuroRec Institute, Professor of Health Informatics, UCL, Visiting Professor, University of Gent

Natalia KAPETANAKI

Professor of Commercial Law at ICHEC Brussels Management School, Assistant at the Center for Private Law, ULB

Greet MUSCH

Director general, Pre-authorization, Federal agency for medicines and health products

Eddy ROMMEL

Managing Director and Co-founder of Rommel Consulting Partners

Solvay Brussels School of Economics and Management, ULB

Anne KORNRREICH

Head, Laboratory Medicine Department, Grand Hôpital de Charleroi

Mattias NEYT

Health economist, Belgian Health Care Knowledge Centre

Florence ROUFOSSE

Associated Head of Clinic and Senior Research Fellow, Department of Internal Medicine, Hôpital Erasme, ULB

Marc TOMAS

Visiting Professor, Université de Namur & Associate Director, Merck-Sharp-Dohme

Dimitris KOURETAS

Professor at University of Thessaly, Greece, Department of Biochemistry and Biotechnology

Jean-Marie NICOLAS

Director, Strategy Support DMPK, Non-Clinical Development Department, UCB Pharma S.A

Marco SCHETGEN

Dean of the Faculty of Medicine, ULB

Marcelle VAN MECHELEN

Coach for Biotech and Biomedical SMEs and scientific consultant BTeBoost SPRL Former Vice President Vaccine Research and Preclinical development GlaxoSmithkline (2012-2015)

Sandrine MARREAUD

Head of Medical and Pharmacovigilance Department, EORTC

Magda PAPADAKI

Lead Technologist, Innovate UK (MSc degree, Oxbridge University, and past member of the Center for BioMedical Innovation at MIT)

Marc PARMENTIER

MD, Professor, Faculty of Medicine, ULB, Director of IRIBHM

Guillaume SMITS

Associated Head of Clinic, Center of Genetics and Hôpital Universitaire des Enfants Reine Fabiola, ULB

Azèle MATHIEU

Professor in Business Planning and Technology Transfer, Solvay Brussels School of Economics and Management, ULB

Alain PARTHOENS

Managing Partner at Vesalius Biocapital

Laure SONNIER

Senior Associate-Health at Interel, previous Senior Officer at Science Europe (Master degree in International Health, Harvard School of Public Health)

Christian MELOT

MD Hôpital Universitaire Erasme, Chef de service Urgences

Thierry PEPERSACK

Professor, ULB, Department of Geriatrics, Centre Hospitalier Universitaire Saint Pierre

Alain DE WEVER

Chairman of the Board, Hôpital Erasme & Professor of Health Economics at ULB

John METSELAAR

Professor of Management Practice at Solvay Brussels School of Economics and Management, ULB

Jean-Paul PRIEELS

Past-Senior Vice-President, global vaccine R&D activities, GSK Biologicals

Olivier WITMEUR

Bernheim Chair in Entrepreneurship, Solvay Brussels School of Economics and Management, ULB

Françoise MEUNIER

EORTC Director of Special Projects (Post-Executive Director)

Yannick QUESNEL

Chief Scientific Officer, ChemCom S.A

Florian TAÛBE

Professor and Head of the Bernheim Entrepreneurship Chair at

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