STUDY GROUP SESSION

Title: **MR in Drug Development**
Day: Wednesday, 11 May 2016
Time: 10:00-12:00
Room #: Hall 405 E

Study Group Committee: Chair, Geoffrey J. M. Parker, Ph.D.; Vice Chair, Detlef Stiller, Ph.D.; Secretary, Alexandre J. Coimbra, Ph.D.; Past Chair, Philip S. Murphy, Ph.D.
2016-2017 Incoming Committee: Catherine D. G. Hines, Ph.D.; Trainee Representative, Georges Hankov, M.Sc.

Overview: A number of MRI techniques have now been used in drug development. These techniques are used at different stages of the drug development process, for assessment of drug effects in preclinical models of diseases, through early stage clinical trials, and even late stage trials. The assessments made with these MRI techniques have been used to inform decisions on whether to continue or stop the development process at different stages (Go/No-go). The decision to use these techniques and the weight given to these assessments in the go/no-go decision making process depends on the level of scientific evidence demonstrating relevance of these assessments for the specific context of use. In many cases, although promising, the scientific evidence of relevance is sparse. In addition, clear evidentiary standards have yet to be established, and related discussions are ongoing in different forums. Of particular interest for drug development are the discussions currently happening with the governmental regulatory agencies overseeing drug development, e.g. the US Federal Drug Administration (FDA) and the European Medicines Agency (EMA). These agencies are the ultimate decision makers as they review all pertinent information to approve of novel therapeutics for human use and commercialization. This session will touch upon each of the above aspects of use of MRI techniques in decision making through the drug development process. The overall goal of this session is to provide a general understanding of (1) the drug development process and how go/no-go decisions are made through the process, and (2) how MRI can influence these decisions.

MR in Decision Making in Drug Development: Internal Go/No-Go, Evidentiary Standards & Regulatory Aspects

10:00	Introducation - Welcome & Business Meeting	Geoffrey J. M. Parker, Ph.D. University of Manchester, United Kingdom
10:15	Drug Development Process & Go/No-Go Decision	Chih-Liang Chin, Ph.D. Merck Sharp & Dohme / MSD, Singapore
10:35	Evidentiary Standards	Alexandre J. Coimbra, Ph.D. Genentech, Inc., USA
10:55	Regulatory Aspects	Patricia E. Cole, M.D.,Ph.D. Takeda, USA
11:15	Discussion Session	MR in Drug Research Committee
11:45	Wrap Up	Geoffrey J. M. Parker, Ph.D. University of Manchester, United Kingdom
12:00	Adjournment	