REGISTRATION DETAILS

Registration: Send your registration before Friday, November 11, 2016 to:

E-mail: drug@uzgent.be

Phone: +32 (0)9 332 00 00

Fees: Non-member: normal rate: €100,-
academia: €50,-
BAPU member: free

Registration fee is payable in Euro by bank transfer to:

IBAN number: **BE82 3101 9136 9568**

BIC/Swift code**:** **BBRU BE BB**

Mentioning: "Symposium 2 December 2016 + name of participant"

Accreditation: REQUESTED
Accreditation for Ethics and Economy / Belgian College of Pharmaceutical Medicine has been requested. Please register yourself on the attendance list at the time of the meeting to apply for accreditation.

BAPU website: www.bapu.be

VENUE DETAILS

Venue:

Marriott Hotel

Korenlei 10

9000 Gent – Belgium

Itinerary:

http://www.marriott.com/hotels/maps/travel/gnemc-ghent-marriott-hotel/

BELGIAN ASSOCIATION OF PHASE-I UNITS

bapu

Symposium

Safety & Regulation in Early Clinical Drug Development

December 2, 2016

Ghent, Belgium

Marriott Hotel

Safety & Regulation in Early Clinical Drug Development

The Belgian Association of Phase I Units (BAPU) has great pleasure in inviting you to its 5th symposium on early clinical drug development. BAPU was founded in January 2005 and represents the Belgian phase I clinical research units located both in pharmaceutical industry and in academia. One of the primary objectives is to facilitate communication and collaborations between Belgian phase I units on the one hand and professional national and international organizations as well as official authorities on the other.

Since the first BAPU symposium in 2006, a European platform has been created with partner organizations in Germany (AGAH), France (Club Phase I) and the United Kingdom (AHPPI) with whom joint European meetings are organized. As a result of this continued collaboration, in 2015 the European Federation for Exploratory Medicines Development or EUFEMED was founded. By joining forces we collectively wish to promote clinical drug development at a European level with the ultimate goal of improving patient care.

Friday, December 2nd, 2016

12:30 Registration and Coffee

13:30 Introduction by the BAPU Chairman
Delphine Malisse

Part I: Safety Aspects in Early Clinical Development

Chair: *Jan de Hoon, Annick Van Riel*

13:40 What makes FAAH so attractive as a CNS target? From bench to clinic.
Mark Schmidt, Johnson & Johnson

14:20 The BIAL 10-2474 Accident: Investigator Site Perspective
Alain Patat, Biotrial, France

15:00 Safety Aspects in Phase I Clinical Research: Regulator's perspective and Recommendations
Walter Janssens, FAHMP

15:30 Panel discussion
Walter Janssens, Mark Schmidt, Alain Patat, Jan De Hoon

16:00 Coffee Break

Part II: EU Regulation – most recent updates

Chair: *Sylvie Rottey*

16:30 EU Regulation: Considerations on Implementation and effects on Early Clinical Research
Diane Kleinermans, Ministry of Health

17:15 Discussion
Diane Kleinermans, Sylvie Rottey

17:30 Goodbye and Reception