BELGIAN ASSOCIATION OF PHASE-I UNITS

Newsletter June 2016

Dear BAPU member,

You are now receiving the 1st Newsletter from BAPU.
This way, the BAPU board wants to keep you informed about new developments and events in early clinical drug development.

Firstly, block your calendar today (if not yet done) for the 2-yearly **BAPU symposium** which is scheduled on 2 December in Ghent. In addition, you are invited to save the date for the first genuine **EUFEMED conference** on Exploratory Medicines Development to be held in London in May 2017.

Your feedback to the initiative of this newsletter would be highly appreciated.

Happy reading!

The BAPU board

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## 1. BAPU symposium 2 December 2016

The focus of our 5th BAPU symposium is on safety aspects in early clinical development. The driver for this symposium is the unfortunate incident, which occurred at the Biotrial Site in France earlier this year. We have some interesting speakers lined up: representation from a sponsor-side providing scientific background (name to be confirmed), Dr. Alain Patat from Biotrial to represent the side of the investigator; as well as a representation from the Agency to provide their reflections. This will be followed by a panel discussion.

In the second part of the symposium Dr. Diane Kleinermans from the Ministry of Health will give an overview of the new EU Regulation on clinical trials and the implementation of it in the Belgian law.

The meeting will take place in the Marriott Hotel in Ghent on 2 December 2016 (1:30 pm - 6 pm).

## 2. EUFEMED Conference May 2017

The first conference of the European Federation for Exploratory Medicines Development, EUFEMED, is scheduled 18-19 May 2017 in London. The AHPPI as local organizer, is hosting the meeting. The programme is in development and is expected to include the following streams: risk management in exploratory drug development, regulatory and operational aspects, scientific innovations and phase I proof-of-concept umbrella protocols.

On 17 May pre-conference workshops are scheduled. There will be a call for poster submissions.

The programme of the 2015 meeting in Brussels can be found here.

## 3. ACCP meeting 25-27 September 2016

**Substantial discount for BAPU / EUFEMED members!**

As EUFEMED together with its members has gained the 'Sister Organisation' status with the American College of Clinical Pharmacology (ACCP), members are entitled to a substantial discount off the registration price. This brings the Early Bird 3-day pricing (valid until 30 June) down from $1,220 to $960 and the Advance pricing from $1,515 to $1,275. This reduction makes it worthwhile becoming a BAPU member!

The 2016 Annual Meeting of the ACCP runs from 25th – 27th September at the Bethesda N Marriott Hotel & Conference Centre in Bethesda, MD. The title of this year's ACCP meeting is "*Clinical Pharmacology: Discovery & Application in the Era of Precision Medicine*".

On 27 September EUFEMED is presenting on "*Establishing Biosimilarity: The European Perception, Experience & Future Trends*" at this ACCP meeting.

A link to the full program is included here.

# 4. Work in progress

## 4.1. Prevention of over-volunteering

For many years we have been aware of an increasing number of healthy volunteers crossing national borders to participate in clinical Phase I studies. As there is currently no European legislation it is difficult to prevent over-volunteering.

In Belgium we have an agreement between all Phase I units to check all volunteers in the VIP Check (private institution, based in Freiburg) system. Unfortunately, the VIP Check system is far from ideal and is only being used by a limited number of research sites in Europe.

Therefore, we are currently evaluating if PSSS (Prefect Search Spider System – developed by University of London and Richmond Pharmacology) could be a good alternative for VIP Check. If PSSS meets our requirements, the perpetual rights to the PSSS system would be given to EUFEMED with the intention to create a European platform for using PSSS.

Belgian authorities will raise the need for a European legislation with the European Commission, EMA and the Clinical Trials facilitation group.

## 4.2. User Acceptance Testing of EU portal/Clinical Trial Application system

A number of EUFEMED members are currently involved in testing the new EU portal. The new portal should harmonize the reporting and approval system for the regulatory process for clinical trials in Europe in the near future. Feedback on the system is consolidated by SGS Belgium. The early involvement of EUFEMED and its members (AGAH, BAPU, Club Phase I and AHPPI) is an important achievement.