DIA Learning

# Post-Authorisation Studies (PAS)

21-22 February 2017
Holiday Inn London Kensington Forum, London, United Kingdom

## OVERVIEW

This course offers insight into EU legislation on PASS and PAES. Examples of PAS protocols as well as some examples of classic pitfalls in study conduct will be presented and discussed. There will be a chance to practice with real life examples, and participants are welcome to provide examples and questions in advance.

A PASS and PAES may be initiated, managed or financed by a Marketing Authorisation Holder (MAH) voluntarily, or pursuant to an obligation imposed by a competent authority. PASS as well as PAES can be integral parts of drug approval and continuous development. A PASS needs multi-departmental input within a company and approval at cross-organisational managerial level. It is the key to applying the right methodology for the correctly identified problem.
**Participants will be provided with preparatory material for the case study that must be read before the course.**

## LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- Understand the concept of PASS
- Understand the concept of PAES
- Discuss the proper study methodology and setting in relation to the safety or efficacy/ effectiveness topic(s) of interest
- Deal with the latest GVP Module VIII requirements for PAS studies
- Understand the new regulation environment relevant to GVP PAS

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

## KEY TOPICS

- GVP Module VIII: Post-authorisation safety studies
- EMA draft scientific guidance on post-authorisation efficacy studies
- Principles of pharmacoepidemiology
- Study types
- Methodology
- Common pitfalls in protocol development

## WHO WILL ATTEND

Professionals who work in:

- Work in late-stage research, peri- and post-approval drug safety, regulatory
- Need to understand the post-authorisation study set up and interpret the data
- Want an introduction to methodologies and/or regulatory framework related to PASS or PAES

Level: Intermediate

## FACULTY

**Michael Busch-Sørensen**
M.D, B.com (marketing),
MPH (Adv. Epi & Biostat), Board Member - Danish Society for Pharmaco-epidemiology
Busch-Sørensen Consulting, Denmark

**Michael Forstner**
Managing Partner, Head of Risk Management & Business Process Management Practice
Mesama Consulting International, Switzerland

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

## DAY 1

**08:00 REGISTRATION**

**08:30 INTRODUCTION**

**09:00 SESSION 1**

### INTRODUCTION TO PAS

*Michael Forstner*

- General introduction and practicalities
- Relevant PASS legislation
  - Directives, regulations and delegated regulations
  - Relevant GVP modules
  - Templates
  - PASS Q&A
- The link between Risk Management, risk minimization and PASS
- How to handle imposed and non-imposed PAS (PASS & PAES) studies i.e. rules for reporting of milestones, amendments and safety data
- ICSR/SUSAR reporting requirements according to GVP module VI

**10:00 COFFEE BREAK**

**10:30 SESSION 2**

### EU GUIDELINES/REGULATION – ONGOING CHANGE

*Michael Busch-Sørensen*

- Clinical Studies (Study types, Risk based approach, Data privacy & verification/validation)
- Benefit/risk post approval: GVP (PAS & Registries) & Adaptive licensing
- PAES Scientific guidance
- Pragmatic compliance with protocols, submissions, reporting etc.

**12:00 LUNCH BREAK**

**13:00 SESSION 3**

### METHODOLOGY

*Michael Forstner*

- Cohort and field studies
- Registries with primary data collection
- Registries based on secondary use of data
- Case control studies
- Issues with multi-country PASS
- Bias and confounding examples

**14:30 COFFEE BREAK**

**15:00 SESSION 4**

### PAS WORKSHOP I

*Michael Busch-Sørensen*

Workshop based on typical pregnancy study. The participants will be provided with real life information making the workshop as close to daily life.

Participant questions submitted prior to the course will be addressed in this session as well.

**16:30 NETWORKING RECEPTION**

**17:30 END OF DAY ONE**

## DAY 2

**08:30 SESSION 5**

### NON-EU GVP GUIDELINES, GVP RELEVANT GUIDANCES, DATA SOURCES ETC.

*Michael Busch-Sørensen & Michael Forstner*

- Revision GCP data privacy prospective vs secondary data
- Implementation of GVP outside EU
- ISPE guidances (GPP, Ethics, Privacy, contracts etc.)
- ENCePP & EU PAS Registry
- CONSORT & study check list

**10:00 COFFEE BREAK**

**10:30 SESSION 6**

### PAS WORKSHOP II

*Michael Busch-Sørensen*

Workshop based on actual reported/published study. The participants will based on the authority request suggest how to design the study and then discuss their proposal vs. the actual approved study.

**12:00 END OF THE TRAINING COURSE**

## Training Course Venue

**Holiday Inn London Kensington Forum**
97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9100
www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 20 to 23 February 2017 at the rate of GBP 120.00 per standard double room for single use per night including full English breakfast, taxes and service fee.

In order to book a hotel room, please contact the hotel directly and quote the booking reference "DIA/QNB".

The room rate is available until 20 January 2017 or until the room block is sold-out, whichever comes first.

## About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

## Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 9 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

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# REGISTRATION FORM

**Post-Authorisation Studies (PAS) # 17535**
**21-22 February 2017 | Holiday Inn London Kensington Forum | London, UK**

DIA Learning

## REGISTRATION FEES

Registration fee includes refreshment breaks, lunch on the 1st day of the course and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

| FEES | MEMBER | NON-MEMBER |
|---|---|---|
| INDUSTRY | € 1'240.00 ❑ | € 1'395.00 ❑ |
| ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME) | € 620.00 ❑ | € 775.00 ❑ |

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

**Payment is due 30 days after registration and must be paid in full by commencement of the course.**

### DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

❑ I do not want complimentary membership

### CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.
**DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.**

### TRANSFER POLICY

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

### PHOTOGRAPHY POLICY

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. **Tel.** :+41 61 225 51 51 **Fax:** +41 61 225 51 52

**Email:** EMEA@DIAglobal.org **Mail**: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
**Web:** www.DIAglobal.org

## ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

Attendee email required for course material access

## PAYMENT METHODS

**Credit cards:** Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID # 17535 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

| Date | Signature |
|---|---|
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