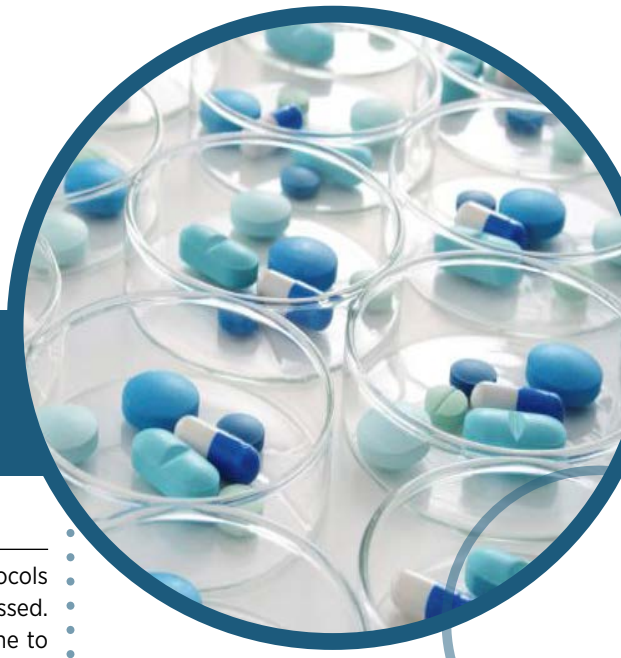
DIA Training Course on

Post-Authorisation Studies (PAS)



13-14 June 2016
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.

LEARNING OBJECTIVES

At the conclusion of this training course, participants wil 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 topic(s) of interest
- Deal with the latest EMA/CHMP/PRAC and EnCePP requirements for PAS studies

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 scientific guidance on post-authorisation efficacy studies
- Principles of pharmacoepidemiology
- Principles of pragmatic trials
- Study types
- Methodology
- Common pitfalls in protocol development

WHO WILL ATTEND

Professionals who work in:

- Clinical Safety and Pharmacovigilance
- Research and Development
- Medical Affairs and Medical Marketing
- Regulatory Affairs
- Comparative Effectiveness, Health Technology Assessment, Evidence-based Medicine

Level: intermediate

DIA DEVELOP INNOVATE ADVANCE

PharmaTrain MASTERING MEDICINES DEVELOPMENT

FACULTY

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

Gro Laier
PV Expert, Grow PV Consulting, Denmark

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DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

DAY 1

08:00 REGISTRATION

08:30 SESSION 1

INTRODUCTION TO PAS
Gro Laier

- General introduction and practicalities
- Relevant PASS legislation
  - Directives, regulations and delegated regulations
  - Relevant GVP modules
  - Templates
  - PASS Q&A

10:00 COFFEE BREAK

10:30 SESSION 2

DETAILS ON EU GUIDELINES
Gro Laier

- Relevant legislation for the distinction between PAS and pragmatic Clinical Trials
- 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.
- PAES legislation and guideline
- Source data verification
- ICSR/SUSAR reporting requirements according to GVP module VI

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
- Pragmatic clinical trials
- Issues with multi-country PASS
- Bias and confounding examples

14:30 COFFEE BREAK

15:00 SESSION 4

CONCERNS OF THE AUDIENCE AND STUDY REVIEW
Michael Forstner

Participants will be asked to submit questions at least two weeks in advance of the course, which will be addressed in plenum.
In addition, two published studies representing different approaches to PASS trials will be made ready for presentation and discussion. Participants will receive a presentation of the issue, develop and discuss a proposed solution in plenum, thereafter the trainers will present what was actually done.

16:30 NETWORKING RECEPTION

17:30 END OF DAY ONE

DAY 2

08:30 SESSION 5

NON-GVP GUIDELINES
Michael Forstner

- Presentation of the EU PAS registry
- Can data on CTs be found public? Clinicaltrials.gov – a presentation
- ENCePP guide in details
- ISPE GPP guide in details
- Specific EMA guidelines

10:00 COFFEE BREAK

10:30 SESSION 6

PASS PREPARATION
Gro Laier

Course attendants will receive examples of safety topics needing a PAS and be requested to prepare a study outline and synopsis. Two of the issues regard safety concerns (one concerning a vaccine), one concerning an efficacy concern and one the need to document the success of a risk minimisation activity.

Slides with the highlights of each issues will be presented before the group work. The groups will be asked to present their study outline in plenum. After the presentations and discussion of the proposed studies, the trainer will present the actual solution as presented in the public domain.

12:00 END OF THE TRAINING COURSE

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 12 to 15 June 2016 at the rate of GBP 160.00 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/XCV".

The room rate is available until 9 May 2016 or until the room block is sold-out, whichever comes first.

Continuing Education

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

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8.5 credits.

SwAPP
Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organiation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

REGISTRATION FORM

Post-Authorisation Safety Studies # 16535
13-14 June 2016 | Holiday Inn London Kensington Forum | London, UK

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course 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

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

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.

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

email (Required for confirmation) 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 # 16535 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