Local Tolerance Testing for Topical Products: From science to regulations

Event #12121
29-30 October 2012
NH Berlin Alexanderplatz, Berlin, Germany

Programme Chair

Daniel M. Bauer
Senior Investigator, Preclinical Safety, Novartis, Switzerland

Programme Committee

Abigail Jacobs
Associate Director for Pharmacology and Toxicology, CDER, FDA, USA

David R. Jones
Expert Pharmaco-Toxicologist, Licensing Division, MHRA, UK

Alexandre Kaoukhov
Senior Clinical Development Director, Allergan, USA

Marc Princivalle
Director of Toxicology, Preclinical Safety Assessment, Director of Toxicology (ERT), Head of Preclinical Safety Assessment at Stiefel, a GSK Company, UK

Overview

Local tolerance testing for investigational topical products is a key element during both non-clinical and clinical safety evaluations. However, scientific knowledge and regulatory expectations appear to be fragmented. This workshop provides a unique opportunity to share best practices among the industry and – even more importantly – to discuss them with feedback from regulatory and academic experts. In addition, understanding different perspectives and elaborating on potential consensus positions may well facilitate the preparation of new regulatory guidance documents during the next years.

Key Topics

- Current and future animal models used for exploratory and regulatory local tolerance testing
- Disease models vs typical toxicology species – how to match clinical conditions?
- Integration of local tolerance testing in general toxicity studies – issues and solutions
- Skin sensitisation testing – value of available pre-clinical and clinical methodology

Who Will Attend

Professionals involved in:
- Non-clinical local tolerance testing
- Non-clinical and clinical safety assessment
- Regulatory affairs
- Research & development of topical topical products

Objectives

- Identify best practices in testing for local tolerance of topical products and highlight potential limitations or typical concerns
- Describe options and strategies, how to integrate non-clinical local tolerance testing into general drug development programmes
- Assess the value of non-clinical vs clinical approaches
- Outline a potential consensus position among industry and regulatory authorities

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available.

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MONDAY | 29 OCTOBER 2012

08:30 **REGISTRATION**

DAY 1 – MORNING TOPIC: LOCAL TOLERANCE MODELS

The way local tolerance questions are addressed experimentally has changed significantly during the last decade. These two sessions will highlight some of the key areas in order to review methodological progress and to pave the way for a more common understanding.

09:00 **Session 1**

STATE OF PLAY: EXPLORATORY AND REGULATORY LOCAL TOLERANCE MODELS

Session Chair:
Daniel Bauer, Senior Investigator Preclinical Safety, Novartis, Switzerland

The Role of the Minipig in Dermal Local Tolerance Testing
Jens Thing Mortensen, Principal Senior Scientist, CiToxLAB Scantox, Denmark

The Murine LLNA in Topical Product Development
Peter Ulrich, Director Preclinical Safety, Novartis, Switzerland

In Vitro Alternatives for Skin Sensitization Testing, the new Paradigm for Cosmetics
Speaker from Cosmetics Europe to be confirmed

10:45 **COFFEE BREAK**

11:15 **Session 2**

DO WE HAVE TO MATCH CLINICAL CONDITIONS?

Session Chair:
David R. Jones, Expert Pharmaco-Toxicologist, Licensing Division, MHRA, UK

Skin Structure and Species Selection for Preclinical Testing
Paul Howroyd, Director of Pathology, Ricerca Biosciences S.A.S, France

The HRIPT: How to match with later clinical use
Klaus-Peter Wilhelm, President and Medical Director, proDERM, Germany

12:30 **LUNCH**

DAY 1 – AFTERNOON TOPIC: SKIN SENSITISATION TESTING

Skin Sensitisation Testing is often perceived to be a highly controversial topic. Indeed, expectations from different disciplines (e.g. non-clinical or clinical), areas of application (e.g. chemicals, cosmetics, drugs), professions (e.g. industry or authorities) and even regions might vary significantly. This session will try to help explain some of these different views and to provide a perspective towards a future testing paradigm for topical products products.

14:00 **Session 3**

DIFFERENT PERSPECTIVES, BUT COMMON UNDERSTANDING?

Session Chair:
Alexandre Kaoukhov, Senior Clinical Development Director, Allergan, USA

Hazard, Risk, Potency and Prevalence: What are we talking about?
David Basketter, Consultant Toxicologist DABMEB, UK

The Value of the HRIPT from a Regulatory Standpoint
Nithyanandan Nagercoil, Medical Assessor, PLAT-2, MHRA, UK

An Industry Perspective
Christian Loesche, Executive Director, Novartis, Switzerland

15:45 **COFFEE BREAK**

16:15 **ROUND TABLE DISCUSSION**
Programme Committee Members and Session Speakers

17:30 **DRINKS RECEPTION**

18:30 **END OF DAY 1**

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

TUESDAY | 30 OCTOBER 2012

DAY 2 – MORNING TOPIC: LOCAL TOLERANCE TESTING PUT INTO PRACTICE

Integration of local tolerance assessment into a general development plan is often a highly complex task. There is a wide range of indications, therapeutic concepts, and pharmaceutical formulations. In some cases, local tolerance data will only be needed on top of existing safety data, but often it will be an integral part for the development of a new molecular entity. These two sessions will provide insights into how different pharmaceutical companies have addressed these needs, considering both the general strategy and individual cases.

09:00 Session 4

INTEGRATION OF LOCAL TOLERANCE TESTING INTO GENERAL DEVELOPMENT

Session Chair:
Abigail Jacobs, Associate Director for Pharmacology and Toxicology, CDER, FDA, USA

LEO Pharma's Strategy for Local Tolerance Testing from Discovery to Development

Preclinical Strategy for the Repositioning of Inhaled Drugs for New Topical Indications
Marc Princivalle, Director of Toxicology (ERT), Head of Preclinical Safety Assessment at Stiefel, a GSK Company

10:45 COFFEE BREAK

11:15 Session 5

CASE STUDIES

Session Chair:
Marc Princivalle, Director of Toxicology (ERT), Head of Preclinical Safety Assessment at Stiefel, a GSK Company

Experience with Different Study Designs in Minipigs and Local Tolerance Testing for Formulation Changes
Sandra Johanssen, Global Preclinical Development, Bayer/Intendis GmbH, Germany

Tolerability in different non rodent species and predictivity for the human situation
Elisabeth Rosner, Director, Novartis, Switzerland

Skin Tolerance as part of Safety Assessment for Cosmetics
Speaker to be confirmed

12:30 LUNCH

DAY 2 – AFTERNOON TOPIC: OUTLOOK

14:00 Session 6

WHAT WILL CHANGE, WHAT WILL STAY?

Session Co-Chairs:
Abigail Jacobs, Associate Director for Pharmacology and Toxicology, CDER, FDA, USA
David R. Jones, Expert Pharmaco-Toxicologist, Licensing Division, MHRA, UK

Do we Expect Changes in the Regulatory Landscape?
Abigail Jacobs, Associate Director for Pharmacology and Toxicology, CDER, FDA, USA

Revision of the EMA Guidance on Local Tolerance Testing
David R. Jones, Expert Pharmaco-Toxicologist, Licensing Division, MHRA, UK

Audience Feedback

15:30 CLOSING REMARKS

HOTEL INFORMATION

DIA Europe has blocked a limited number of rooms at the following hotel:

NH Berlin Alexanderplatz
Landsberger Allee 26-32
10249 Berlin
Tel: +49 30 422 61 30
Fax: +49 30 422 61 3300
Email: nhberlinalexanderplatz@nh-hotels.com

at the special rate of EUR 99.00 per room/day including breakfast per person/day.

To reserve a room, please contact the hotel directly at: nhberlinalexanderplatz@nh-hotels.com

IMPORTANT: To be assured of accommodation at the hotel, registrants are recommended to complete their reservation by 14 September 2012. Reservations received after this date are subject to availability and room rate may vary.

REGISTRATION FORM

Local Tolerance Testing for Topical Products: From science to regulations
29-30 October 2012 I NH Berlin Alexanderplatz, Berlin, Germany

ID # 12121

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If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day. * All fees are subject to local German VAT of 19%

Early-bird rates available for members:

Register by 17 September 2012

Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. **Does not apply to government/charitable/non-profit/academia members.**

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Join DIA now to qualify for the member rate	€ 115.00 ❑

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TOTAL AMOUNT DUE: €_____ NOTE: PAYMENT IS DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION. 12121DIAWEB

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Payments must be net of all charges and bank charges must be borne by the payer.

CANCELLATION POLICY: All cancellations must be in writing and received with DIA Europe by 17:00 CET on 19 October 2012

Cancellations received by the date above are subject to an administrative fee: Full Meeting Cancellation: Industry (Member/non-member) = € 200.00. Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. Regretfully, if you do not cancel by the date above and do not attend, you will be responsible for the full registration fee. You are responsible for cancelling your own hotel reservations. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA Europe is not responsible for airfare, hotel or other costs incurred by yourself.

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 DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA Europe Postfach, 4002 Basel, Switzerland