

## InterAction Executive Summit on **Building the Drug Safety Body of Knowledge**

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Two-day meetings in two centers to identify opportunities, align interests and establish actions needed to enrich practice

Philadelphia, PA (April 25–26) & Basel, Switzerland (May 30–31)

### A Dynamic Approach to Industry Collaboration

These workshops introduce an innovative approach to creating an “on-demand” interactive forum for experts from the pharmaceutical industry, academia and service/technology industries in a collaborative, non-competitive working environment.

Through face-to-face meetings blended into and supported by a collaborative software environment, participants will have a unique and ongoing opportunity to share information and viewpoints on optimal development, monitoring, and promotion of pharmaceutical products to minimize risk to patients, prescribers, and the industry.

Participants will also get the opportunity to identify and interact with key collaborators, subject matter experts, valuable information sources, and industry experts working at the forefront of developing practices and new business models.

This group will focus on the development of a “Drug Safety Body of Knowledge”, required to meet the clinical, regulatory, legal, and commercial needs of pharmaceutical companies in the years to come.

Before the meeting, all participants are encouraged to submit short presentations of their viewpoint – their needs, their vision, their potential contribution – on the website as a form of introduction to the other participants.

Each session will begin with short “briefing” presentations provided by experts in the field. “**Background**” case studies will be utilized where appropriate to support discussion. “**InterAction**” topics, proposed in the program but modified and expanded by the participants themselves, will be used as the basis for promoting dialog. During the meeting, participants will be able to identify and focus on the most important topics for ongoing practice enrichment, solution development, and collaboration.

After the meeting, key presentations, case studies and follow up discussion/action outlines will be posted online in the collaboration environment which will remain a source of continuously updated information and secure communication for all qualified group members.

The InterAction amongst working groups formed at the initial meetings will continue through a series of regional (face-to-face) and regional/global virtual (web/teleconference) meetings using the online InnovationWell collaboration environment.

## What we want to achieve....

- Enhance the organizational appreciation and use of drug safety knowledge throughout product development and clinical use
- Enhance drug safety knowledge transfer to R&D teams
- Enhance clinical research knowledge transfer to pharmacovigilance personnel
- Optimize the application of new tools in drug safety-related decision making e.g., *in silico* modelling
- Manage the uncertainty in drug safety decision making

## ...and how we'll go about it

- By the formation of "Practice Enrichment" working groups aligning business partners, academia and peers on non-competitive issues
- Through enabling continued collaboration among participants working to identify opportunities for practice enrichment in drug safety, pharmacovigilance and risk management; share insights and recommendations in live collaboration over the web and InterAction meetings
- By identifying high priority actionable approaches for building the Drug Safety Body of Knowledge

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## Building the Drug Safety Body of Knowledge

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Each meeting comprises four half-day sessions designed to identify opportunities, align interests and establish actions needed to enrich practice.

The structure of the meetings is designed to maximise interaction between participants as the formal presentations can be seen beforehand on the InnovationWell website.

**Introduction:** History, Status, Drivers of Change by Dr Sidney Kahn (PvRM, Inc) who will talk about the business issues of our current situation and how we got here, the regulatory and other public health initiatives, and the societal expectations.

### Sessions

- ▶ Business Opportunities, Challenges & Strategies
- ▶ Knowledge Integrative Strategies & Approaches
- ▶ Support Systems for Drug Safety Knowledge Management
- ▶ Knowledge Transfer and Product Life Cycle Management

## 1. Business Opportunities, Challenges & Strategies

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- ▶ How do we reduce the risks of unanticipated medically important adverse effects for new products?

### InterAction Topics:

- Develop “safety first” commercialization strategies
  - Implement a “prospect and explore” safety management strategy
  - Conduct safety studies and meta-analyses throughout the product lifecycle, especially in the peri-launch period
  - Modify current candidate selection decision making processes, e.g., promote objective decision criteria – ensure safety objectives are appropriate for the indication
- ▶ How do we make better use of available drug safety knowledge and expertise when selecting new drug candidates? How do we bring greater transparency to these decision making processes?
- ### InterAction Topics
- Enhance dissemination of drug safety knowledge
  - Align drug safety expertise and knowledge aggregation to a single safety function
  - Implement internal processes to ensure all potential safety concerns are identified, recognized, and evaluated
- ▶ How do we react more effectively to potential safety signals available from clinical trial and healthcare delivery information?
- ### InterAction Topics
- Can a legal/regulatory “Safe Harbor” be constructed to promote objective evaluation of potential safety signals?
  - Establish “peer reviewed” safety signal triage processes
  - Establish corporate policies and procedures supporting identification, evaluation and management of safety signals
- ▶ How do we partner more effectively with physicians and patients to reduce the potential for serious adverse drug reactions?
- ### InterAction Topics
- Establish direct drug safety communication channels with physicians and formularies, provide real time information to assist physicians in detecting and managing adverse effects
  - Compensate physicians for real time adverse event reports to the manufacturer to improve timeliness and quality of information (strategy: What we don’t know, WILL hurt us, eventually!)
- ▶ How to better manage benefit-risk expectation(s) for new product introductions?
- ### InterAction Topics
- Pursue a clinical “Disease Management” marketing strategy, i.e. how the drug enhances management of the disease
  - Compare alternative therapeutics openly and with “patient-oriented safety criteria”

## 2. Knowledge Integrative Strategies & Approaches

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- ▶ How do we better integrate drug safety knowledge throughout the product lifecycle to minimize the risk to patients, providers, and the business from medically significant adverse effects?

### InterAction Topics

- Mandate “interoperability” for product safety information, i.e., across data systems, documentation and business processes
- Build integrative knowledge-based systems for aggregation and analysis of product safety information
- Mandate records management capabilities to ensure availability and awareness of product safety information throughout the lifecycle

- ▶ How can electronic systems be employed to better store, share and integrate drug safety knowledge relevant to marketed products?

### InterAction Topics

- Accumulate an actionable knowledge-base of drug safety information, provide tools to enhance the value of existing drug safety knowledge e.g., develop drug safety ontologies to support inference
- Represent information in “interoperable” forms to enable aggregation across systems
- Establish systems with “transparent” user interactions and highly effective data visualization to maximize “internalization” of drug safety knowledge

- ▶ What knowledge management approaches can be used successfully to enhance sharing of drug safety knowledge among domains of expertise?

### InterAction Topics

- Implement internal/external expertise location capability for drug safety information
- Establish competency enrichment practices for drug safety, e.g., Lessons Learned, Communities of Practice
- Establish a practice enrichment intervention to enhance decision making skills under typical conditions of uncertainty

- ▶ What is the definition of an adequate Drug Safety Body of Knowledge? What techniques are needed to build and maintain it?

### InterAction Topics

- Identify key information forming the market’s current “Drug Safety Body of Knowledge”  
i.e. what are health authorities, payors, and providers looking at to support their perception of safety?
- Determine which adverse effects should be prospectively tested for and when; identify those for which additional trials are required
- Determine product exposure needed to evaluate long term adverse effects
- What issues would trigger additional evaluation or studies to prospectively enhance drug safety knowledge for a product

### 3. Support Systems for Drug Safety Knowledge Management

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- ▶ How can we categorize drug safety knowledge to improve "interoperability" in multiple contexts and systems?

#### InterAction Topics

- Identify key current and needed diagnostic/bioinformatics information sources to predict high impact adverse effects
- Identify key drug safety data and supporting systems
- Identify drug safety metadata and/or ontologies required to expand the Drug Safety Body of Knowledge

- ▶ What should electronic tools, databases and systems do to better capture and re-use drug safety knowledge?

#### InterAction Topics

- Map high impact adverse effects to key drug development predictors, where known and possible
- Implement drug safety decision support systems with simple user interfaces and highly integrated drug safety data
- Correlate performance of predictive drug safety approaches with categories of investment in IT systems

- ▶ How do we obtain faster and more reliable safety signal information in data from clinical trials and/or clinical practice?

#### InterAction Topics

- Aggregation and correlation of data from clinical trials and post-market sources
- Enhance collection and analysis of Phase IV study information
- Identify high impact opportunities for industry/payor/health authority data set aggregation

- ▶ What modeling techniques can we deploy to better include safety knowledge in drug candidate selection decisions?

#### InterAction Topics

- Identify superior methods & tools for semantic classification and retrieval of knowledge
- Identify approaches for the improved transfer of knowledge between Enterprise systems, user applications and work processes
- Demonstrate productivity gains and value from advanced search technologies

## 4. Knowledge Transfer and Product Life Cycle Management

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- ▶ How to improve the knowledge and learning support of patient populations?

### InterAction Topics

- Identify strategies and methods to improve knowledge flow to patients
- Identify restrictions & opportunities arising from regulatory issues
- Review support systems for patient knowledge transfer and learning

- ▶ How to publish and manage delivery of new drug safety knowledge to partners, payors, providers and patients?

### InterAction Topics

- Identify specific requirements of recipients of safety knowledge
- Review classification and distribution methods of safety knowledge
- Identify opportunities in safety knowledge-based services
- Review potential impact of current regulatory initiatives, e.g. FDA SPL and e-labeling

- ▶ How to increase innovation and returns from product life cycle and intellectual property management of drug-related knowledge?

### InterAction Topics

- Enhancing innovation and value with product life cycle management
- Intellectual property management of drug safety knowledge

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## Meeting Format & Locations

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The InterAction meetings are intended to maximise participant interaction through a unique format that utilises current technology to disseminate knowledge **before and after** the conference, so that time spent **at** the conference can be used to bring out critical ideas in key note presentations, case studies, roundtable discussions, Q&A sessions, exhibitor demonstrations, workshops, networking events and individual meetings.

The dual-center approach means that participants can choose to attend the Executive Summit either in Philadelphia or in Basel, but will automatically have access to all the online components from the other meeting and be able to communicate via the web facilities. The program for both meetings will have variation on talks, topics, and discussion leaders, but otherwise will address similar issues and themes of the knowledge-based drug safety management program.

### Pre-Event

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- Key Issues and Case Studies will be defined by the organising advisory board and presented to all participants
- All participants are invited to present a seminar with audio through the community web site starting March 1, 2005. These presentations may be used to describe a solution or strategy, experiences gained from past projects (whether positive or negative), or to describe their requirements for future solutions
- Group Discussions, via the web and phone-based teleconferences, will be initiated and conducted during this pre-meeting period to promote theme development for the meeting

## During the Event

- The format is designed to enable significant interactions in small groups and one-on-one discussions driven by a problem-solving agenda, including generic case study, customer-supplied issues, strategies, integrative approaches etc.
- Presentations at the InterAction Meetings are intended to act as a starting point for break-out sessions and so will be kept relatively short and concentrate on main points of view, key ideas, proposals or findings and to summarize pre-event presentations. Ample time will be allocated for Q&A for each speaker, as well as panel discussion times with each session
- A limited number of vendors will have the opportunity to display and discuss their products, not only within the current context, but also to gain vital input for the development of future products
- A Summary of Issues by the Chair will start both meetings
- Lunch & Dinner: the formats of these will also be designed to maximise mixing and interaction among participants.

### **Session Format**

- Each session comprises short summary presentations of approx. 8 mins. (plus 5 mins. each for Q&A)
- General discussion of topic between members of panel and audience (approx. 30 mins)
- Coffee Break
- Break-out workshops & discussions

## Post-Event

- Summaries and reports from both face-to-face meetings will be published on the site for participants
- Community members may access seminars, reports and discussions through the web site regardless of whether they were able to attend either face-to-face meeting or not
- Community of practice 'white papers' on the main themes will be developed and expanded on the web site through both the web conferences and face-to-face meetings

## Web Facilities

The following facilities will be made available to participants and members of the community through the website:

- Presentation slides with audio, and summaries and reports from both face-to-face meetings
- Tools are provided to post comments and questions on the materials
- All participants have the opportunity to submit a presentation or position paper for viewing by other participants and members
- All participants can access the names, biographies and photos submitted by other participants and can exchange messages between each other

Please visit the website [www.innovationwell.net](http://www.innovationwell.net) for later updates to the program.

## Conference Calls

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All available seminars with audio may be accessed from the Web site at any time. Phone-based conference calls for group discussion and question-time will be held periodically, according to the schedule provided below. Please note that this schedule is subject to change: most recent scheduled times for upcoming conference calls are posted on the web site (Schedule section of [www.innovationwell.net](http://www.innovationwell.net)) and are alerted to participants via e-mail.

Participants may submit questions through the Web site prior to calls, can call in to the live conference call, or can access the call recordings which are subsequently made available through the Web site. Participants will be issued conference call invitations and instructions via e-mail and must confirm call participation at least one day in advance of the conference call day.

Conference calls are held at 12.00 EST (Eastern Standard Time) and normally have a duration of approx. 60 minutes.

**Note:** 12.00 EST = 9.00am California, Noon New York, 5pm London, 6pm Zurich, 9.30pm Mumbai

### Schedule for Philadelphia

Weds Mar 30	Business Opportunities, Challenges & Strategies
Weds Apr 6	Knowledge Integrative Strategies & Approaches
Weds Apr 13	Support Systems for Drug Safety Knowledge Management
Weds Apr 20	Knowledge Transfer and Product Life Cycle Management

### Schedule for Basel

Weds May 4	Business Opportunities, Challenges & Strategies
Weds May 11	Knowledge Integrative Strategies & Approaches
Weds May 18	Support Systems for Drug Safety Knowledge Management
Weds May 25	Knowledge Transfer and Product Life Cycle Management

## Locations

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### InterAction in Philadelphia (April 25–26)

Marriott Courtyard Hotel  
21 Juniper Street  
Philadelphia, PA 19107  
Tel: +1 215 496 32 00  
Fax: +1 215 496 36 96

### InterAction in Basel (May 30–31)

Swissôtel Le Plaza (A Raffles International Hotel)  
Messeplatz 25  
4005 Basel, Switzerland  
Tel: +41 61 555 33 33  
Fax: +41 61 555 39 70

(Please note that the meetings and lunch will be held at the hotel's nearby conference facilities at L'Entrée, Riehenring 118)

### Accommodation

Participants are responsible for arranging their own accommodation. However, we have arranged special rates at the above hotels if you provide the special code 'Drug Safety' when making your reservation.

## Submissions

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All participants are invited to submit presentations to be shared with other members and meeting attendees before the InterAction Meetings. These presentations can include audio seminars (we'll organise the production for you), Powerpoint slides and/or further supplementary materials such as short position papers of 2–6 pages.

Please note the following deadlines for each meeting:

- **Abstracts** must be submitted for consideration before **March 31** for the Philadelphia meeting and **April 30** for the Basel meeting.
- **Presentations** must be submitted before **April 15** for inclusion in the program for Philadelphia and **May 15** for inclusion in the Basel program.

Abstracts should be submitted to: [innovationwell@douglasconnect.com](mailto:innovationwell@douglasconnect.com)

## Opportunities for Sponsors & Exhibitors

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- Various sponsorship opportunities are offered for either/both InterAction Meetings. Please contact the organisers if interested in supporting a Session, Meal or Networking Event, or Web Community activity.
- A limited number of Exhibitors will have tabletop presence in the vicinity of coffee-break and networking events. Exhibitor slots will be assigned on a first-come-first-served basis. Exhibitors are also expected to participate in the pre-event sessions on the website with their product presentation, so that they can devote their time at the conference to discussing specific issues, solutions and requirements. We encourage Exhibitors to bring a representative from their Product Development to participate in discussions on what enhancements are needed for future products.

## Registration

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You can apply to participate in the InnovationWell InterAction Meetings in Philadelphia or Basel using the registration form with this document or online through the Community's website at [www.innovationwell.net](http://www.innovationwell.net), but please note that places are very limited.

We strongly encourage you to include a short biography (approx 300 words) and photo which we can share with other participants before the meetings as this will help reduce the time needed for introductions and facilitate the arrangement of individual meetings. Please send these bios to [innovationwell@douglasconnect.com](mailto:innovationwell@douglasconnect.com).

We also encourage you to apply for membership to the InnovationWell CoP for Knowledge Management in Pharma & Life Science as this will give you not only access through the website to presentation material and discussions occurring around the meetings, but will also give you the chance to take part in the Community's other activities and regular virtual seminars and conferences.

Drug Safety Knowledge Management – InterAction Meeting Registration Form				
Spring 2005	Philadelphia USA	Basel Switzerland	Members	Non-members
Two-Day InterAction Meeting Registration* (includes access to InnovationWell® for 1 month pre- & post- meeting)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> \$900	<input type="checkbox"/> \$1100
Membership* (provides access to InnovationWell® for 12 months post- meeting)				<input type="checkbox"/> \$400
Exhibitor (includes one InterAction Meeting Registration & Exhibitor Tabletop Space)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> \$1800	<input type="checkbox"/> \$2000
We are interested in Sponsoring		<input type="checkbox"/> Event	<input type="checkbox"/> Session	<input type="checkbox"/> Networking Meal

Name

Company/Institution

Dept./Job Title

Company Address

Tel.

Email:

Payment

Visa

MasterCard

Invoice

Credit Card No.

Exp. Date (MM/YY)

Name on Credit Card (if different from above)

Date

Signed

Please send or fax to: Dr Barry Hardy, Community Coordinator ([innovationwell@douglasconnect.com](mailto:innovationwell@douglasconnect.com))  
 Douglas Connect, Baermeggenweg 14, 4314 Zeiningen, Switzerland eFax: +44 870 112 38 44