

# THE TOPRA Roundtable



An occasional series examining current issues in regulatory science



## Benefit-risk legislation:

**Do recent regulatory changes introduce new legal risks or improve balance in the courts?  
Can moves to reduce regulatory burden compromise safety and increase liability in the courts?**

### Benefit-Risk of a medicinal product is the cornerstone of regulatory science.

This Roundtable will address current state of the art methodologies to evaluate benefit/risk balance in the context of a rapidly changing legislative and regulatory framework world-wide.

The Benefit-Risk concept has to incorporate the acceptance of risk of adverse events both as it affects the individual patient or consumer and collectively in the community at large.

#### The components of this include:

- The clinical prognostic risk; the socio-economic and environmental risk;
- The potential legal risks as regards product liability and consumer protection and safety, intellectual property
- Potential commercial and possible risks of criminal sanctions together with medical and ethical issues.

#### The following issues will be comprehensively discussed in the first of this exciting new debating series:

- Economic and societal pressures to reduce the regulatory burden on the development of healthcare products so that innovative new therapies can be made accessible faster.
- Improving toxicology and pharmacology methodologies
- More efficient yet robust clinical trial paradigms
- Improved biostatistical and data analytical methods
- Methods to predict benefit/risk earlier in clinical development programmes
- Enhanced administrative procedures such as conditional licensing to ensure faster authorisation of medicines into the market place without compromising safety.

### About the TOPRA Roundtable Series

TOPRA has developed this new debating series to provide high quality knowledge exchange and facilitate networking with key stakeholders within Regulatory Affairs. The series will cover subjects that are always highly topical and have an immediate impact on the work of the regulatory professional.

#### Programme

- 5pm Networking over tea and coffee
- 5.30pm debate opens with moderator, **Alan Hunter**
- Opposing/complementary views from:

**1** The Regulatory viewpoint: **David Jefferys**, (TOPRA President and Eisai), who will outline the background to the new legislation, the concept of benefit /risk from a regulatory viewpoint and why industry welcomes the change

**2** The Legal viewpoint: **Alison McAdams**, Partner DAC Beachcroft LLP, who will set out the legal issues, new concept, how will the courts react to this and what are the new issues posed.

- Followed by open debate with the floor
- Summary by **Peter Feldschreiber**, MHRA/4 New Square Lincoln's Inn
- Close 7.15pm
- Dinner at 7.30

This event, the first of a new series, will enable delegates to debate key issues with each other and the speakers, which is unique in the regulatory events calendar. TOPRA is taking networking and debating to a new level. Make sure you're part of the debate

*To book, please complete the form overleaf and fax back to +44 (0) 207 537 2003*

**Date:** 13 September 2012

**Venue:** The Royal Society, London, UK

**Reference:** RT12/1

**Lifelong learning (LLL):** 2 hours

#### Fees:

**Meeting and dinner:**  
£168.00 = £140.00 + £28.00 (20% GBVAT)

**Meeting only:**  
£90.00 = £75.00 + £15.00 (20% GBVAT)

email: [meetings@topra.org](mailto:meetings@topra.org) tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: [www.topra.org/roundtable1](http://www.topra.org/roundtable1)

**Date:** 13 September 2012 **Venue:** The Royal Society, London, UK

**BOOKING FORM 2012**

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On receipt of your booking form we will confirm your provisional place in writing and provide directions to the venue. An invoice will be sent separately. To ensure admission, payment must be received prior to the meeting.

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## Fees

### The TOPRA Roundtable – Benefit-Risk

Meeting and Dinner:  **£168.00** = £140.00 + £28.00 (20% GB VAT)

Meeting only:  **£90.00** = £75.00 + £15.00 (20% GB VAT)

*The VAT rate charged will be the prevailing rate at the time of invoicing*

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### Please note:

Fee excludes accommodation and travel.

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All cancellations must be received in writing 28 calendar days before the start of the course and will be subject to a cancellation fee of £35 plus VAT. Payment can be in Euro or Sterling.

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