Statistical signal detection

PROTECT Symposium tutorial

Andreas Brückner, Gianmario Candore, Jim Slattery, Niklas Norén
European Medicines Agency, London, United Kingdom
Feb 18, 2015
## Agenda

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<td>Introduction + 3 perspectives on statistical signal detection in practice</td>
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<td>14.45 – 15.30</td>
<td>Introduction to disproportionality analysis</td>
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<td>15.30 – 15.45</td>
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<td>Pitfalls of disproportionality analysis</td>
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<td>17.45 – 18.00</td>
<td>Questions and closing</td>
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VigiBase®

120 countries

10 million reports
Signal detection process

By international experts

SIGNAL!

In-depth review

Dismissed

Initial review

Already known

Dismissed

Statistical signal detection

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WHO Collaborating Centre for International Drug Monitoring
Analyses of Adverse Reaction Reports in the WHO Database - April 2006

Signals in this issue

- Laryngeal and severe cutaneous reactions
- Epigastric pain and use of nonsteroidal anti-inflammatory drugs
- Seizures of brainstorm and limb weakness during the use of diphenhydramine and other antihistamines
- Urticaria, angioedema and anaphylactic shock
- Infections and unusual infections
- Respiratory and liver toxicity

Follow-up

- Withdrawal and spontaneous recovery
- Position and market withdrawal
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- Office and group lycopersic
- Reactions from the NCI
- Professor from the NCI
- Pharmaceutical and matrix cleanse
- Response from Taking

WHO PHARMACEUTICALS NEWSLETTER

The WHO Pharmaceuticals Newsletter provides you with the latest information on the safety of medicines and legal actions taken by regulatory authorities around the world. It also provides signals from the Uppsala Monitoring Centre's SIGNAL, document. We thank you for your interest in this publication and wish you a healthy and fulfilling year in 2013.

Contents
- Regulatory matters
- Safety of medicines
- Signal
- Feature

No. 4, 2012
Disproportionality analysis

Anno 1998