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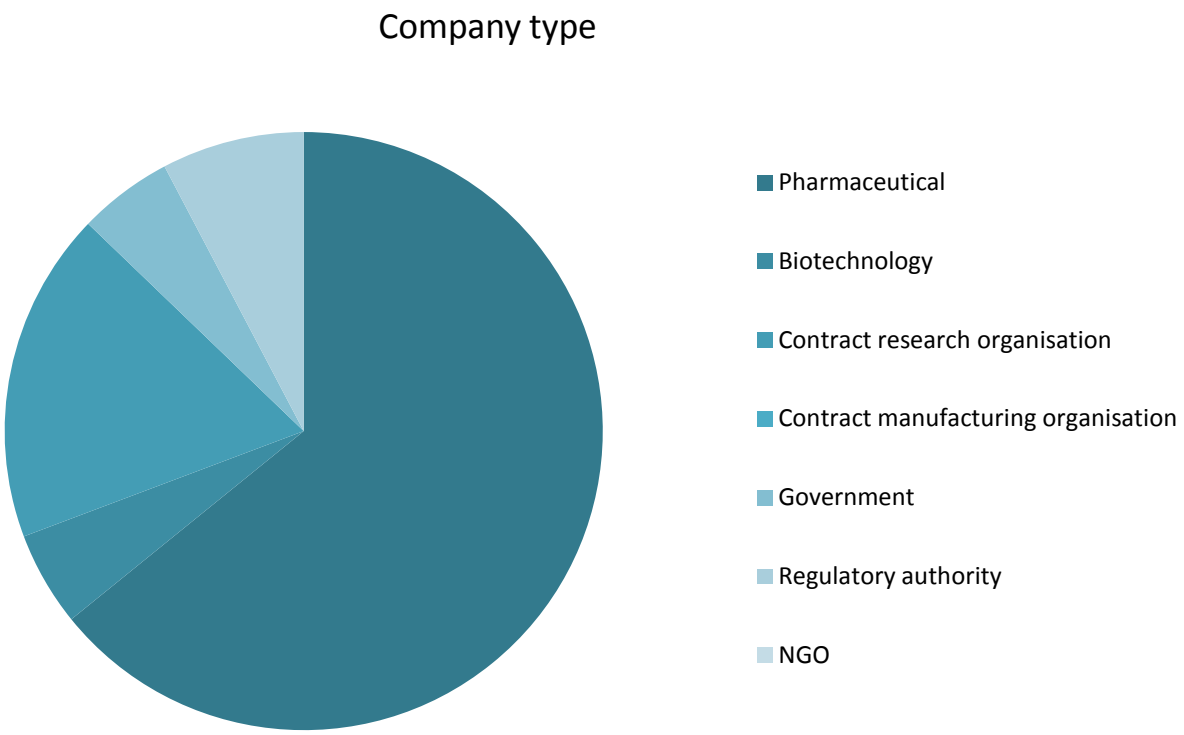
Industry survey report

We recently sent a survey to a cross section of drug safety industry representatives. The responses highlight the key areas of interest to the industry as well as identify some of the major challenges facing the industry on a day to day basis.

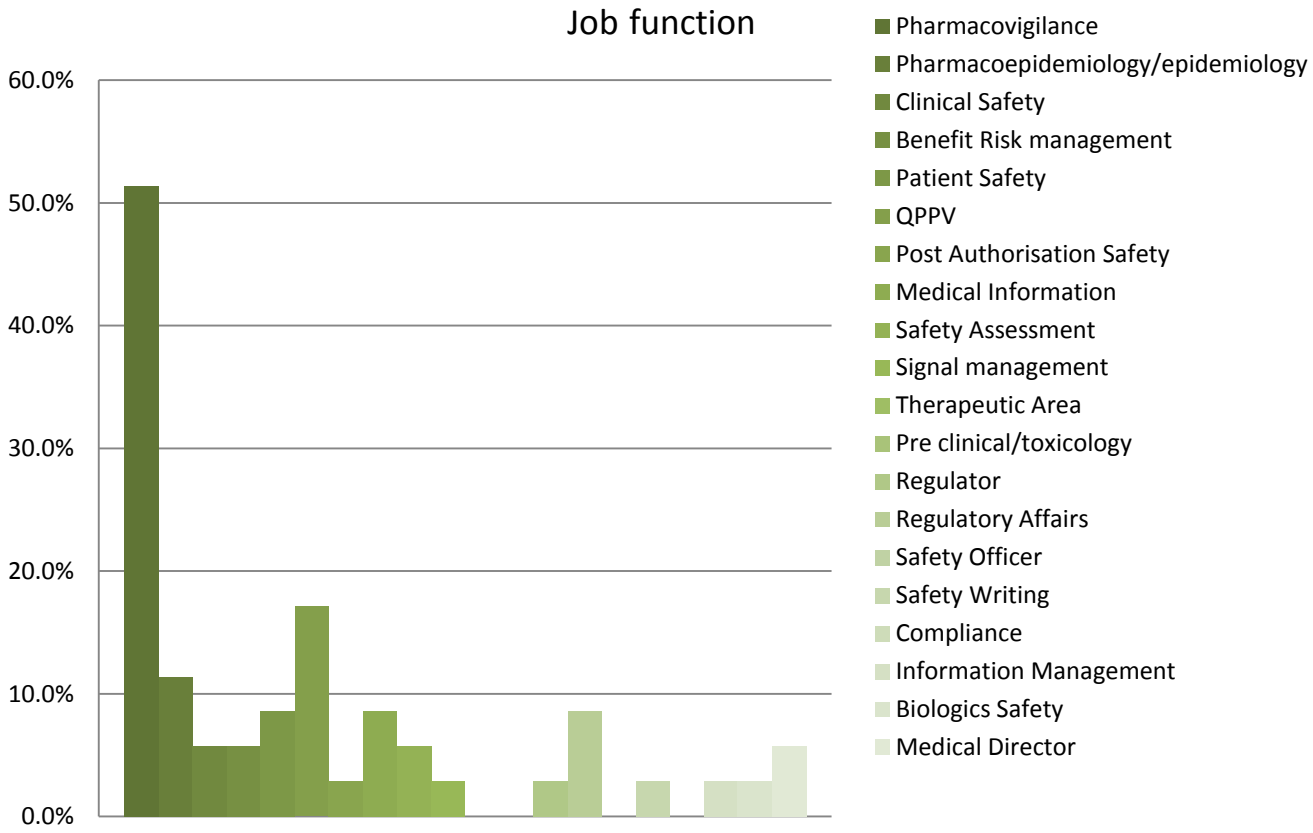
The report has been used as part of the development process for the agenda of the World Drug Safety Congress Americas 2013, taking place in Boston on 24-25 April 2013.

Want to have your say?
http://www.surveymonkey.com/s/drugsafety
Want more information?
http://www.healthnetworkcommunications.com/wds
Any comments?
afairchild@healthnetworkcommunciations.com

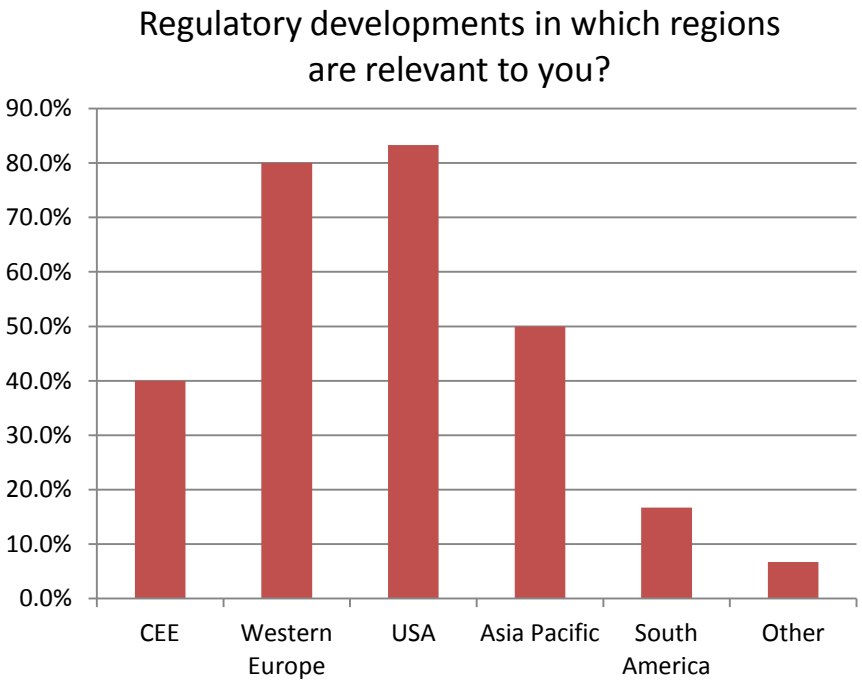
Profile



Profile


Job function
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
Pharmacovigilance
Pharmacoepidemiology/epidemiology
Clinical Safety
Benefit Risk management
Patient Safety
QPPV
Post Authorisation Safety
Medical Information
Safety Assessment
Signal management
Therapeutic Area
Pre clinical/toxicology
Regulator
Regulatory Affairs
Safety Officer
Safety Writing
Compliance
Information Management
Biologics Safety
Medical Director

Topic Focus: Regulatory Environment



Which specific countries?

Asia Pacific
Belgium
Brazil
Canada
CEE
China
Cyprus
Denmark
Europe
France
Germany
Greece
India
Ireland
Israel
Japan
Kenya
UK
USA

What have been the most significant recent global regulatory changes for drug safety?

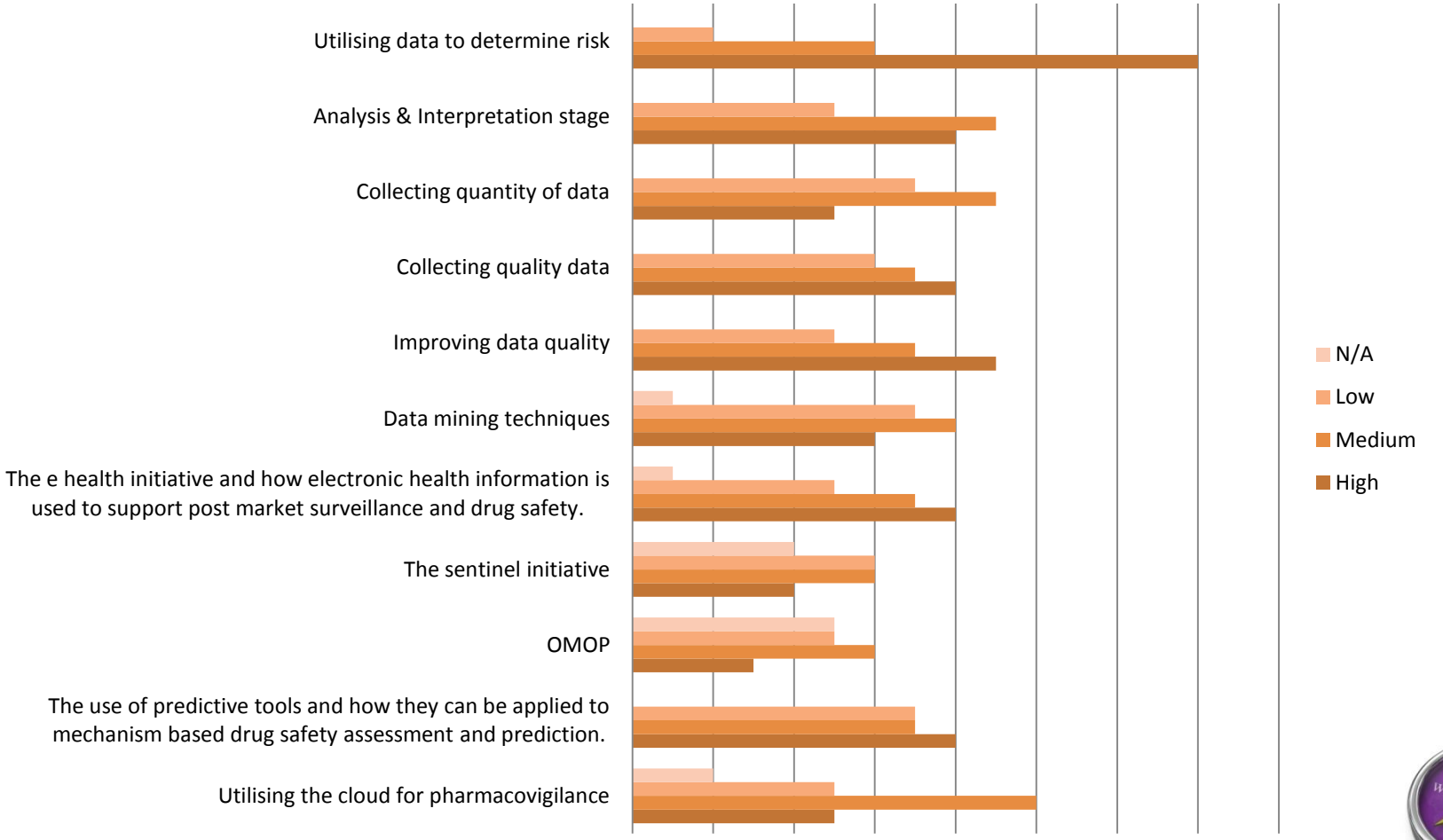
Some key feedback:

-Implementation of GVP
-Development of the PSMF
-New EU legislation
-REMS implementation
-Risk management in Asian Markets
-PBRER
-Safety of novel drug combinations
-FDA reporting requirements

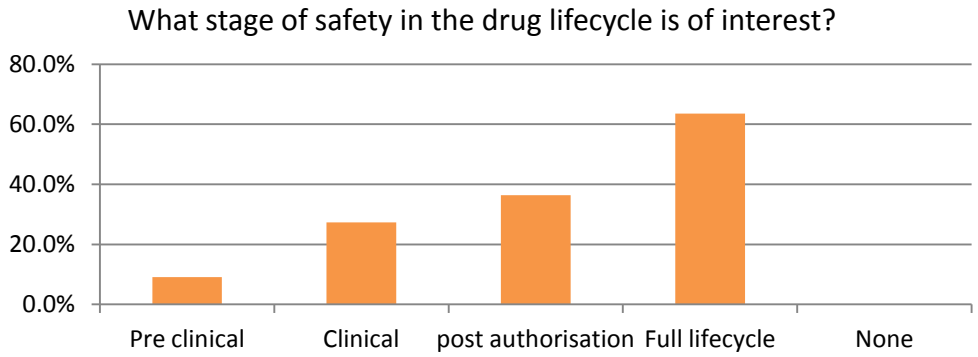
The regulatory environment shapes the day to day decisions and processes of drug safety professionals. The regulatory setting and changing policies are of key importance to the industry and was highlighted as one of the topic challenges of today. 2012 saw the roll out of the biggest changes to the European regulatory environment in recent times. This is a global issue, which is impacting international organisations and those operating in Europe. The survey demonstrated that Europe is of key importance, though the international perspective is still needed with USA and Asia both being of importance as well as some emerging markets such as CEE and South America.

Topic Focus: Safety Data

How important are the following data management system topics to you?



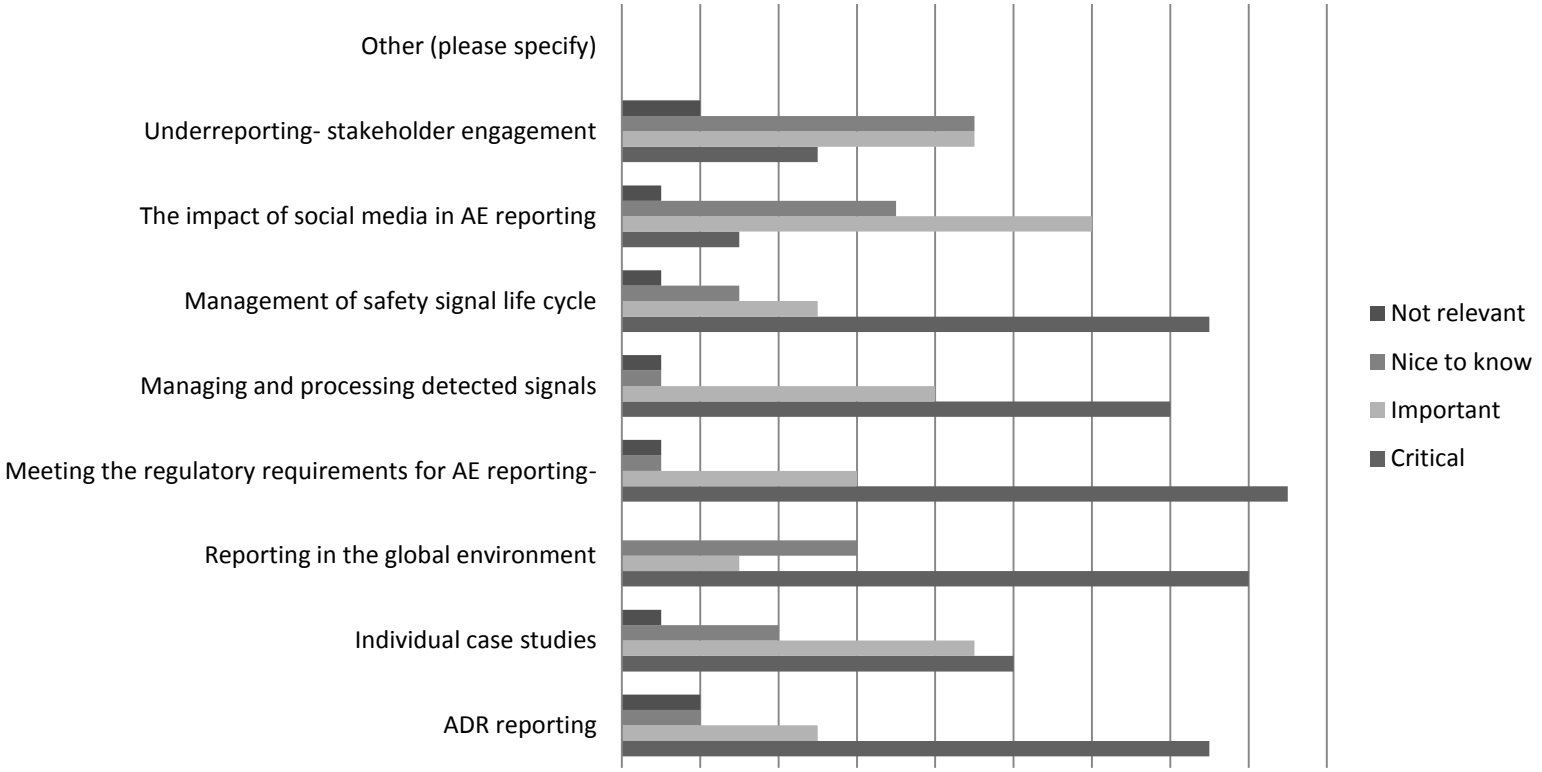
Topic Focus: Safety Data



The right data management strategy will enhance safety throughout the lifecycle of a drug by streamlining and speeding up the identification, classification and response to ADR and AEs. The survey response shows a significant interest in how to utilise data to determine risk and a strong interest around the theme of collecting the quality and quantity of data needed to satisfy regulatory and internal pharmacovigilance and risk management purposes.

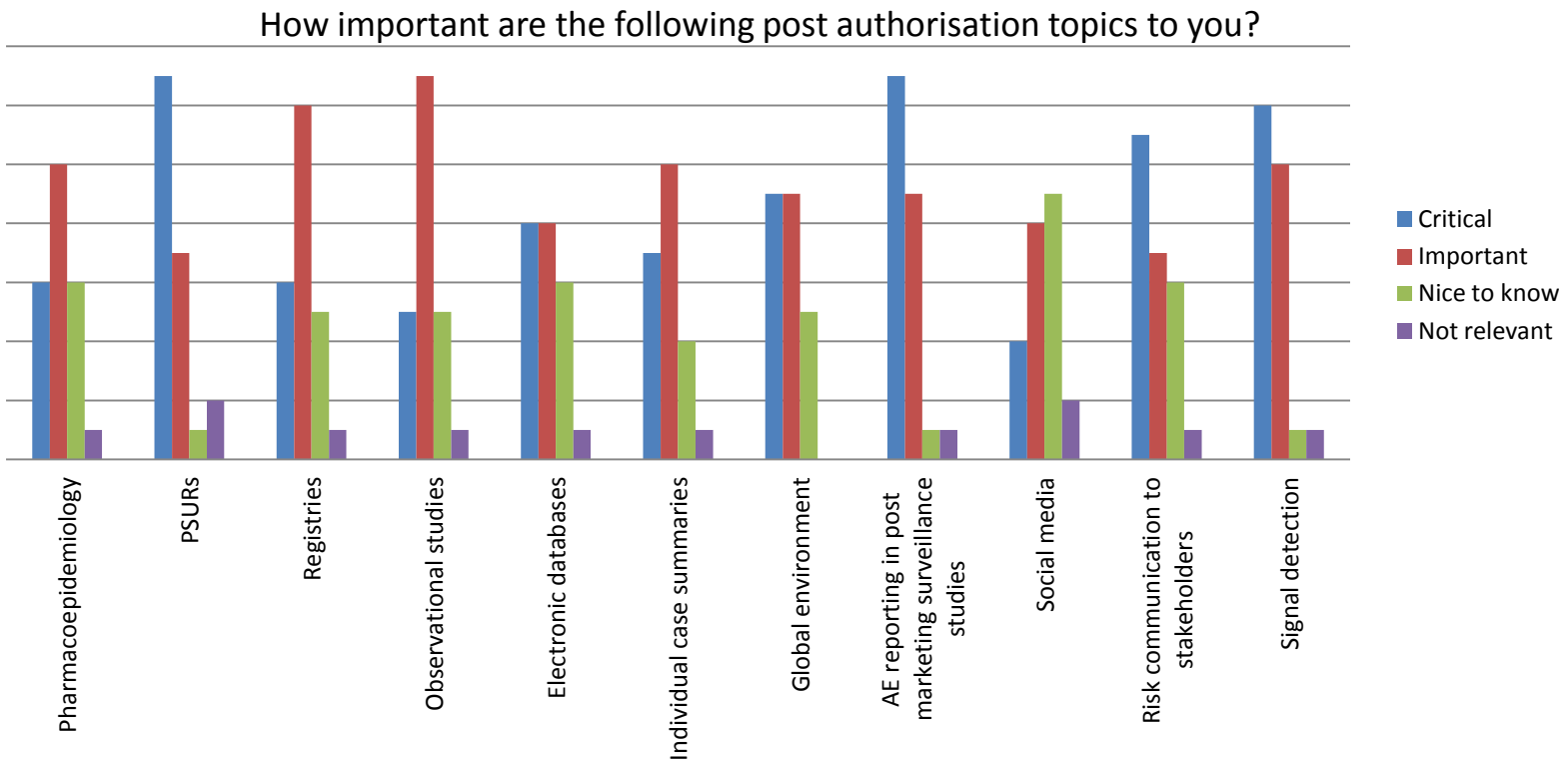
Topic Focus: Signal Management

How important are the following signal detection/ reporting topics to you



As always signal detection and management is a priority for the industry. In the survey several topics were highlighted as of critical importance including ADR reporting, reporting in the global environment, meeting regulatory AE requirements, signal processing and management. This demonstrated the need to better understand regulatory and internal requirements for safety signals, develop the right reporting system for your drug and process the signals efficiently and effectively. These are all core elements of creating a sound tracking and processing system.

Topic Focus: Post Marketing Safety



Late phase pharmacovigilance strategies are complex due to the sheer numbers and scale of trials needed to satisfy regulatory and market access requirements. It is a key area of importance to the industry with several areas highlighted as of importance. The topics that were received the biggest response rate were PSURs, Post marketing surveillance studies, signal detection and risk communication to stakeholders. Other areas that were highlighted as important were registries and observational studies.

We'd love to meet you too…

We're hosting the **World Drug Safety Congress Americas 2013** in Boston and would love to see you there.

Drug Safety Industry leaders will discuss:

- International drug safety landscape
- Global regulatory overview and recent developments
- Increasing complexities affecting the management of drug safety
- Data management and electronic submissions
- Financial and logistical constraints
- In-depth look at clinical safety & the limitations to pre-marketing safety

& much more!

It's a business event

World Drug Safety Congress Americas 2013 will provide you with key insights into the drug safety challenges affecting you and give you an excellent opportunity to discuss these diverse issues in a conference format.

For more information on the event visit www.healthnetworkcommunications.com/wds