



Scientific Community

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What is the Scientific Community?

- The pvnet and pvconnect Scientific Community is a forum for discussing PV related queries of a specific and imminent nature
- The Scientific Community is available to all staff of a pvnet and pvconnect member companies' PV Organisation
- The Scientific Community consists of:
 - A searchable library of previously discussed queries
 - A bi-monthly teleconference to discuss experience, practices and where possible conclude best practices for 3 to 4 member queries
 - A network of member Scientific Community contacts to provide insight into their companies practices
- This is supported by the Scientific Community website



Simplify what you do



How can the Scientific Community help me?

- Does the same issue keep reoccurring in management meetings apparently because there is no clear answer?
- Are you receiving pressure from regulators to perform activities over and above, or differently to how you are internally interpreting regulations?
- Are you internally reviewing a PV activity or organisation and are keen to not reinvent the wheel?
- Are you developing activities in an area currently outside the scope of regulations and are keen to understand any accepted norms or practices?

The Scientific Community can provide you with insight into other members experiences, practices, issues and if there is any current view of good or best practice



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How can I access to the Scientific Community?

For pvnet members: <http://pvnet.wcigroup.com>

The screenshot shows the pvnet website interface. At the top, there is a navigation bar with tabs: "About pvnet™", "Benchmarking", "Scientific Community", and "Downloads". The "Scientific Community" tab is highlighted. Below the navigation bar, there is a "Latest Announcement" section and a "Forthcoming Events" section. A yellow callout box with a black border points to the "Scientific Community" tab and contains the text: "1. Select Scientific Community tab". Another yellow callout box with a black border points to a Windows login dialog box that is overlaid on the website. The dialog box is titled "Connect to securenets.wcigroup.com" and contains the text: "Connecting to securenets.wcigroup.com." Below this text, there are two input fields: "User name:" with a dropdown menu and a "..." button, and "Password:" with a masked input field. At the bottom of the dialog box, there are "OK" and "Cancel" buttons. The background of the dialog box shows the pvnet website with various logos, including Abbott, Boehringer Ingelheim, Merck Serono, Roche, and Sanofi Aventis.

1. Select Scientific Community tab

2. Enter Company Access details (available from your Scientific Community Contact Point)

How can I access to the Scientific Community?

For pvconnect members: <http://pvconnect.wcigroup.com>

The screenshot shows the pvconnect website interface. At the top, there is a navigation bar with tabs: "About pvconnect™", "Benchmarking", "Scientific Community", and "Downloads". The "Scientific Community" tab is selected. Below the navigation bar, there is a "Latest Announcements" section. A yellow callout box points to the "Scientific Community" tab with the text: "1. Select Scientific Community tab". Another yellow callout box points to a login dialog box that is open over the website. The dialog box is titled "Connect to securenets.wcigroup.com" and contains fields for "User name:" (with a dropdown menu showing "companyname") and "Password:". Below the fields are "OK" and "Cancel" buttons. A second yellow callout box points to the "User name:" field with the text: "2. Enter Company Access details (available from your Scientific Community Contact Point)". The background of the website shows various pharmaceutical logos such as Actavis, Alcon, IPSEN, Johnson & Johnson, King Pharmaceuticals, Lantheus, Novartis, Nycomed, Orion Pharma, Purdue, Ucb, and Watson.



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How do I search the Scientific Community library?

The screenshot shows the 'pv scientific community' website. At the top, there is a search bar with the text 'This Site' and a magnifying glass icon. Below the search bar, there are several sections: 'Next Meeting', 'Meeting Summaries', and 'Questions for Next Meeting'. The 'Next Meeting' section displays a table with columns for 'Title' and 'Location'. The 'Meeting Summaries' section displays a list of summaries with columns for 'Type' and 'Name'. The 'Questions for Next Meeting' section displays a table with columns for 'Type' and 'Name'. There are three callouts: one pointing to the search bar, one pointing to the 'Next Meeting' section, and one pointing to the 'Questions for Next Meeting' section.

pv scientific community

Welcome PV/NET-01\abbott

This Site

Home

Next Meeting

Title	Location
27 July 2010 Scientific Community Teleconference NEW	+44 (0) 20 7075 1520 pincode 611858#

Meeting Summaries

Type	Name
	2010-05-Submitting
	2010-05-Solicited Reports
	2010-05-Quantitative Signs
	2010-05-QC on ICSRs NEW
	2010-05-Literature Searches
	2010-05-Lack of Efficacy NEW
	2010-05-Interpreting the EMA Guideline and Templates for preparing EU Risk Management Plans NEW
	2010-05-Procedure to send SUSAR line listings from IND studies to investigators in Hungary NEW
	2010-05-Handling ICSRs for NEW
	2010-03 Vol 10 In
	2010-03 SUSAR Rep
	2010-03 Surveillance and
	2010-03 MHRA Requirement
	2010-03 Medication Errors
	2010-03 Global and Local Co
	2010-03 Frequency of Local
	2010-03 Electronic Reporting
	2010-01 Processing Pregnant
	2010-01 Issuing Multiple Invest
	2009-11 Reporting of Ex US Spontaneous Reports for US Investigational Products

Questions for Next Meeting

Type	Name
	22/06/2010 14:36
	22/06/2010 14:36
	22/06/2010 14:36
	22/06/2010 14:36
	22/06/2010 14:36
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:35
	21/04/2010 22:37
	21/04/2010 22:37
	26/11/2009 14:03

There are no items to show in this view of the 'pvscicom questions' document library.

1 - 20

Enter search criteria here

Search Tips:
Think broadly and be aware of company specific language
E.g. An 'Investigator Letter' may also be referred to as an Investigator 'Notification' or 'Mailing'

Details of next teleconference can be viewed here

View summaries of previously discussed queries here.
Click on individual query to view detail
All summaries are dated

Queries currently under review in preparation of next teleconference can be downloaded here

What will I find in a query summary?

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Global and Local Co-Marketing Information

Responding companies
Amgen
AstraZeneca
Gilead
J&J
Novartis
Novo Nordisk

Question from Abbott

Topic Category: Safety Agreements

Related Meeting Summaries:
None

Information Components

1. Identification of all licensing partner
 - Abbott defines global agreement multiple countries and are negotiated by agreements are specific to local
 - Abbott defines local agreements are negotiated by agreements are specific to local
2. Management of Co-marketing agree
3. Sales data

Summary:
Abbott's process for obtaining the above 1 stakeholders. It can be challenging to identify types of agreements, variations in agreement identifying who manufactures the product experiences of other companies in order business.

- Responses are broad ranging and detailed
- Many members are left with complex information complicated by years of involvement
- There is a preference to enable local responses

WCI: Core concept of PV identification of new licor is supported by the following framework.

- Process-oriented, collaborative in
- Awareness of pharmacovigilance
- Timely notification to all parties

Specifically, it should be agreed in an SOP that Lic agreement so that Safety can provide the PV-spec licensing/marketing/distribution agreements, the 'PI' in a consistent, template format within the safety department. In general, one party within the agreement can be designated responsibility for the maintenance of the safety

t. What is your mechanism for identifying II
WCI: Recommended practice is that there is required personnel, to monitor compliance a agreements. To be situated within PV because

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Global and Local Co-Marketing Information for PSURs

compliance with reporting timelines in agreements with Regulatory Authorities. However an SOP should clarify the process by which necessary groups such as legal or marketing provide information to the PV department in a consistent and complete manner.

Company 1: Have a global SOP for International Safety must approve a pharmacovigilance agreement with all license partners.

a. Is there a group responsible for monitoring/managing and communicating the status of agreements?
Company 1: All agreements must be saved in a global contract management system – product safety keeps a log.
Company 2: There is a licensing team within drug safety that works with the marketing group responsible for external business deals.
Company 6: Response: Yes Patient Safety/PV
Company 7: Yes
If so, which organization holds the responsibility? (Regulatory, PV, Marketing, Other)
Company 4: Groups within the PV organisation manage global and local agreements.
Company 5: We maintain a listing of known agreements that we circulate to commercial, legal and regulatory each month to check any changes in territories or agreements. In addition we are notified by legal as a general rule of new license arrangements so we can draft the SDEA.
Company 7: Commercial.

b. When planning for a PSUR what is the scope of marketing agreements considered for the PSUR (Global versus Local agreements)?
WCI: Here, the scope of the PSUR needs to be clarified. A PSUR required for a local product has different scope implications than does a PSUR required for a global product. In general, it is advisable to follow the procedure outlined by Company 4:
Company 1: Partners send their individual reports on a regular basis as stated in the agreements, cases are included just as cases directly received by us.
Company 2: In both situations, one company is designated as being responsible for the PSUR within a subordinate pharmacovigilance agreements.
Company 4: Depends on whether the Marketing Partner is actively engaged in development or a distributor. Collaboration in authoring is included in the Pv Agreement when applicable. For distributors, a clause will indicate their obligation to provide information as applicable (issues, studies, HA interactions etc.) PSUR authors refer to global agreements. Generally, single country agreements are the responsibility of the local Operating company.

Date of query

Members contributing to response

Related Queries

References & Definitions

Summary

Blinded detailed responses

Conclusions, Best Practices and WCI Point of View where appropriate (more planned for 2010)

How do I ask a question?

- Each member company has a Scientific Community Contact Point, nominated by your Head of Safety
- If you want to know who your contact point is contact pvnetsc@wcigroup.com
- Please submit your query to your SC Contact Point by the final query submission date (see following slides), who will then submit your query to the Scientific Community



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How do I structure a query?

1. Reference to similar queries found by searching the Scientific Community Library
2. Explanation of all company definitions used and details of regulations referred to
3. Short summary explaining background to query
4. List of questions

Please keep queries to 8 to 10 key questions, the findings and conclusions from which can be discussed during a 20-30 minute item at the teleconference

What happens to my query once submitted?

- A check is performed against the subject matter of the query to avoid duplication and repetition
- Queries are formatted and circulated to all member Scientific Community Contact Points with a request to provide details of your company's practices and experience
- Your SC Contact Point circulates these queries your the relevant subject matter experts
- SC Contact Points return these responses to pvnet@wcigroup.com or deborah.gold@wcigroup.com
- Collated Summaries of Responses are posted one week prior to teleconference to enable review



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Can I share my company's experience confidentially?

- Yes
- All responses you provide prior to a teleconference will be blinded and any company specific references removed
- Your company name will be listed as a respondent at the top of the page to provide context for other members and a Company Number randomly generated to identify your responses
- Current and previous experience and points of view shared on the Scientific Community teleconference is for the benefit of the other attendees and will not be documented



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When are the Scientific Community teleconferences?

- The Scientific Community teleconferences are held bi-monthly on the last Tuesday of the month
- Final date for submission of queries is 4 weeks prior to this
- Dates 2010/2011:

Teleconference	Final Query Submission Date
Tuesday 27 th July 2010	Tuesday 29 th June 2010
Tuesday 28 th Sept 2010	Tuesday 31 st Aug 2010
Tuesday 30 th Nov 2010	Tuesday 2 nd Nov 2010
Tuesday 25 th Jan 2011	Tuesday 28 th Dec 2010
Tuesday 29 th Mar 2011	Tuesday 1 st Mar 2011



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Are there any future plans for the Scientific Community?

To increase awareness of the Scientific Community across the membership and encourage greater participation on the teleconferences the following are under consideration:

- Send notification of posting of final summaries of Scientific Community queries to all members
- Maintain contact groups for all interest areas (e.g. Risk Management, Signal Detection, Operations, QPs, etc) to enable direct invitation to contribute to particular query discussion
- Hold themed Scientific Community teleconferences (e.g. PV Sourcing, Social Media)



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I have some ideas to improve the Scientific Community, what should I do?

- We are always looking to build on the value of pvnet and pvconnect to members. Please send your suggestions to deborah.gold@wcigroup.com
- You will be contacted to explore and clarify your suggestion
- Significant changes will be discussed at Annual and Mid Year Forums to ensure formal membership approval



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