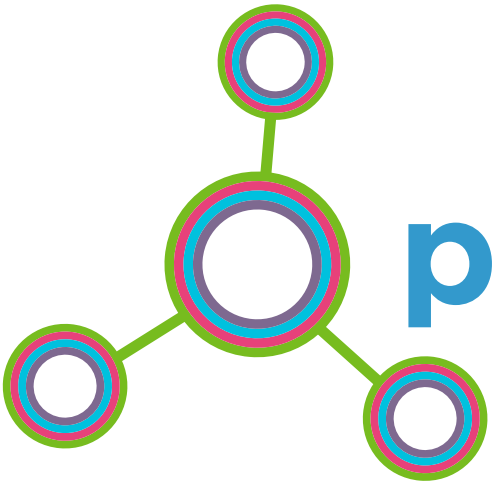


pvlegal

A specialized forum for
in-house counsel working on
pharmacovigilance issues in
the Life Sciences sector

what is pvlegal?

pvlegal is a membership-based forum for in-house counsel working on drug and device safety issues in the Life Sciences sector.

what sets pvlegal apart?

- pvlegal is a truly industry-led group; the members determine and customize the agenda for each meeting.
- pvlegal members elect a chairman from amongst the membership who directs the substance of pvlegal meetings and communications, with input from the membership.

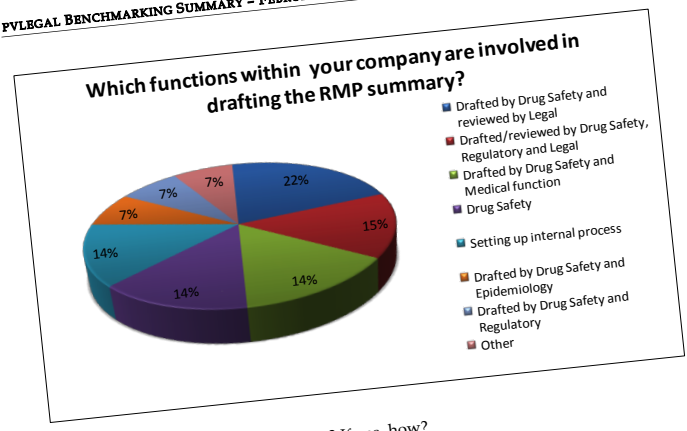
objectives

- Share and benchmark best practices in the area of pharmacovigilance.
- Facilitate the exchange of knowledge and ideas relating to current challenges, and develop relationships among member companies' in-house counsel.
- Facilitate direct interactions with industry leaders, self-regulatory bodies, and key government regulators/enforcement agencies.
- Keep members updated regarding the latest legal and regulatory developments and enforcement trends in the area of drug and device safety around the world.

membership benefits

- Biannual in-person meetings
- Semi-annual conference calls to discuss recent relevant developments on pharmacovigilance, as well as enforcement developments and trends
- Benchmarking reports, prepared based on questionnaires tailored to the interests of the members
- Updates and alerts on relevant legal and regulatory developments
- Access to a members-only, password-protected website with pharmacovigilance background resources and pvlegal work product
- Unique networking opportunities
- Antitrust supervision
- Resources of Sidley Austin LLP's outside counsel on non-company specific questions and the proposal of possible legal solutions to generic problems and issues encountered collectively by member companies

Examples of graphs and text from benchmarking reports



Is your Legal department involved? If yes, how?

…mbers stated that Legal is or will be involved in drafting or reviewing

…olved in drafting or reviewing the

PVLEGAL BENCHMARKING SUMMARY – FEBRUARY 2013 MEETING

3. What stages of product development are covered by your Global Benefit-Risk Committee (*e.g.* products in development, approved products, line-extensions etc)?

- Thirteen members stated that all stages of product development are covered by their Global Benefit-Risk Committee.
- Comments:

  - "All stages of product development are covered by our Global Benefit-Risk Committee, but we have a separate committee dealing with pre-clinical aspects".

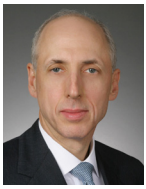
  - "The Committee covers the entire life-cycle of our products, from inception to post-market".

  - "Our Committee covers investigational products at all stages and also post-marketing data".

  - "Within our company the team is formed during Phase I and continues throughout marketing."

- One member did not respond or did not consider the question pertinent.

pvlegal contacts



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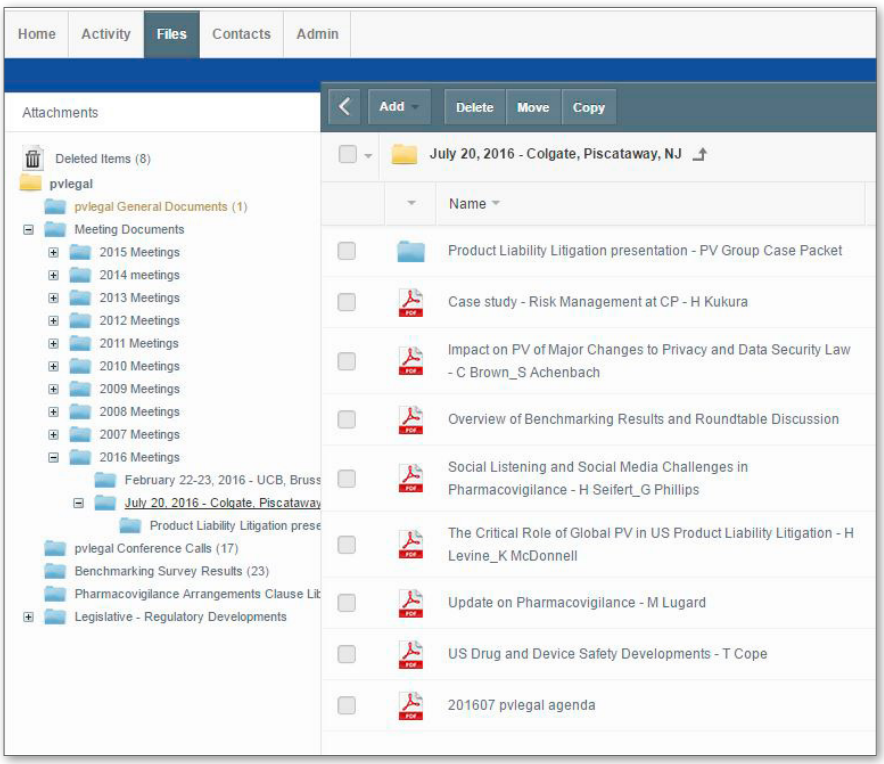
pvlegal Extranet: Members-only access to reports, meeting materials, pharmacovigilance resources and member contact directory



Other Life Sciences Legal Forums

aclegal
Anticorruption compliance

ctlegal
Clinical trials

dplegal
Data privacy

MN-1335 05/16