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Observations from the Post-Approval Summit

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“We are moving to an age of active surveillance and this will create new issues, but also solutions,” said Richard Gliklich, MD, Harvard Medical School and president and chief executive officer of Outcome Sciences. This past week high-level speakers from industry, government and academia gathered at the Post-Approval Summit held at Harvard Medical School, to discuss various post-approval topics. To view the agenda, go to www.postapproval.org. Gliklich served as the Summit’s Chairperson.

Whereas four years ago, drug safety was the up-and-coming topic at the conference, this year the hot topic was comparative effectiveness or CE. Gliklich noted that talk of CE started at last year’s conference. “In the next three to four years, there is going to be a lot of movement in this area. It’s a common thread among industry, government, payers, academia, and the discussion around it is ‘we need it and it’s time to tackle it.’”

CE compares one product or therapy versus others in the real-world. Ideally, CE will provide the right evidence at the right time and it will be increasingly important for product commercialization. Gliklich refers to www.graceprinciples.org for descriptions and definitions in the CE area.

More from the Summit

CDER Director Janet Woodcock, MD, presented the FDA’s view on all issues post approval. The FDA still needs to sort out how to accomplish Congress’s vision, and how to apply its funding to achieve these broad mandates ranging from active surveillance systems to REMS. As we’ve reported in *Applied Clinical Trials*, some of FDA’s money is going toward a hiring spree and there was talk of getting more scientific-level personnel on the postapproval side vs. the pre-approval side where they current reside.

“Case Study: Creating an Active Surveillance System” was presented by Richard Platt, MD, professor of ambulatory care and prevention, professor of medicine, Harvard Medical School. Active surveillance is mandated by a \$25 million FDA back, but hindered by privacy issues and is “clearly” in the very early stages.

REMs and RiskMAPs were also discussed. It is still unclear, because the FDA is still staffing up for post-approval, how many REMs will be on the table this year.

For more information on CE, please check back to *Applied Clinical Trials*' June issue of View from Washington as Jill Wechsler reports from Capital Hill the latest developments.