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| **psi-logo**  **psi-strapline** | PSI’s Pharmaceutical Statistics  Journal Club    **In association with the DIA presents**  **Clinical Trial Safety Monitoring**  **7th September 2017**  **3:00-4:30pm BST**  UK Dial in: 0203 695 0088 US Dial in:+1 408 638 0968 Access code: 643 284 892  <https://diaglobal.zoom.us/j/643284892> | **PST2** |

**DISCUSSANT: Dr Ram Tiwari (FDA)**

**SPEAKER: Dr Patrick Schnell (The Ohio State University College of Public Health, Columbus Ohio)**

**A Bayesian Exposure-Time Method for Clinical Trial Safety Monitoring With Blinded Data**

Authors: Patrick Schnell, Greg Ball.

Therapeutic Innovation & Regulatory Science, Vol 50(6), p833-838, 2016

**SPEAKER: Dr Hui Quan (Sanofi, New Jersey)**

**Adaptive and repeated cumulative meta-analyses of safety data during a new drug development process**

Authors: Hui Quan, Yingqui Ma, Yan Zheng, Meehyung Cho, Christelle Lorenzato, Carole Hecquet

Pharmaceutical Statistics, Vol 14, Issue 3, May/June 2015

For each of these published papers there will be a 20 min presentation by the author followed by 20-25 min discussion.

Papers available to view prior to the meeting on <http://www.psiweb.org/events/journal-club> and presentation slides will be available there to download a week before the JC. Journal subscribers can access papers at any time. Audio recordings will be available shortly after the JC to download from the above website.

Open to PSI and non-PSI members – no need to pre-register.

We encourage you to read these papers in advance so you get the most from this event.

Where multiple people are dialling in from the same site, we encourage you to book a meeting room and dial in together.

For further info/feedback, or to submit a question to the authors in advance of the meeting please contact [journalclub@psiweb.org](mailto:journalclub@psiweb.org)



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