Aydin Erenmemisoglu, J Bioequiv Availab 2015, 7:5
http://dx.doi.org/10.4172/0975-0851.S1.021

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6th World Congress on
Bioavailability & Bioequivalence:
BA/BE Studies Summit

August 17-19, 2015 Chicago, USA

Possible mistakes and manipulations in bioequivalency trials

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Sponsors are spending billions of money to register their drugs. There are number of GCP, bioanalytical centers and CRO's around the world in that business. BE/BA trials are designed and done with upmost care to protect subjects welfare and safety. When the outcome is positive, this is mostly product developer's success. If the trial fails then everybody blames the Principal investigator about the unwanted results. The clinical center staff starts troubleshooting and tries to find-out possible mistakes through the clinical trial. They check all the quality records, the video recordings and monitoring reports. Are they looking right places? Sometimes the answer is yes. But there are some special cases that come out with surprising consequences. Those cases demonstrate that scientifically perfect designs could be ruined with uncalculated behaviors of subjects or staff. The Clinical sites and Principal investigators can avoid such consequences with right precautions and taking measures with root cause analysis. Those possible techniques could be documented and be part of quality system of GCP center.

Biography

Aydin Erenmemisoglu has graduated from Ankara University Medicine Faculty in 1985. He held title of Assistant Professor at Erciyes University, Medicine Faculty, Pharmacology Department in 1995 and Professor in 2001. He is Principal Investigator of Erciyes University DEKAM GCP Centre and has completed 1400 BA/BE studies as well as Phase I & II.

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