

Bibliography

Placebo in Hypertension Adverse Reaction Meta-Analysis [Pharm] Study - The following articles are included as background for this session:

Al-Khatib SM, Califf RM, Hasselblad V, et al. 2001. Placebo-controls in short-term clinical trials of hypertension. *Science* 292:2013-2015.

Lipicky RJ on behalf of PHARM investigators. 2006. Placebo hypertension adverse reaction meta-analysis of death and dropout original case report forms.

Mangano DT. 2003. Clinical review of events in the PHARMA study.

Basile JN & Chrysant S. 2006. The importance of early antihypertensive efficacy: the role of angiotensin II receptor blocker therapy. *J. Human Hypertension* 20:169-175.

Addendum 4/17/2006 - The following article was added as background for the April 26, 2006 PHARM Study session of the Cardiovascular and Renal Drugs Advisory Committee meeting:

Brass, E.P. et.al. (2006) "Risk Assessment in Drug Development for Symptomatic Indications: A Framework for the Prospective Exclusion of Unacceptable Cardiovascular Risk." *Clinical Pharmacology & Therapeutics*. Vol. 70 No. 3: 165-172.