**Title:** Participation of Women and Sex Analyses in Late Phase Clinical Trials of New Molecular Entity (NME) Drugs and Biologics Approved by the FDA in 2007-2009

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**Primary Interest Area (TRACK 9):** Regulatory Affairs and Science, Quality, and GXP Compliance

**Abstract Keyword:** FDA Reviews, Late-Phase Clinical Trials, Women’s Participation, Sex analysis

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**Abstract Objective:** To track women’s participation in late-phase clinical trials (LPCTs) of New Molecular Entity drugs and biologics approved 2007-2009. Furthermore, to assess FDA reviews for sex-based analyses and examine labels for sex-based dosage recommendations.

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**Abstract Method:** 57 New Drug Applications (NDAs) and 11 Biologics License Applications (BLAs) were accessed from FDA Electronic Document Rooms and evaluated for women’s participation. Sex analysis was tracked in FDA Reviews and drug labels were reviewed for dosage recommendations by sex.

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**Abstract Results:** Sex-specific (n=5) and pediatric (n=3) drugs were excluded. Women’s participation was 39%, 48%, 42% (NDAs) and 49%, 62%, 58% (BLAs) for 2007, 2008, 2009, respectively. 74% of NDAs had safety and efficacy sex analysis. 100% of BLAs had efficacy sex analysis. None had dosage recommendations by sex.

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**Abstract Conclusion:** Women’s participation in NDA LPCTs averaged 44% in 2007-2009 and varies widely by indication. The 2001 GAO reported 52% for 1998-2000. This study showed that NDA sex-analysis of both safety and efficacy has increased since the GAO report of 72%.

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