Salma Lemtouni; Albert DeFelice; Kathleen Uhl; James Willard
FDA, Silver Spring, MD

Introduction: FDA lacks the regulatory authority to enforce adequate enrollment of women, ethnic minorities and elderly subjects in drug research to evaluate differences in response to drugs.

Hypothesis: The number of females (F), Blacks (B) and other ethnic groups enrolled in anti-hypertension (HTN) drug trials is not proportional to the prevalence (P) of HTN in these subpopulations.

Method: Data from 590 short-term (4 – 8 w) placebo-controlled trials of 42 drugs and their combinations are used to conduct descriptive analyses of participation and drop-outs by demographics.

Results: 86,137 patients were randomized and 9,636 patients dropped-out for reasons including therapeutic failure, CV and non-CV adverse events, and administrative reasons.

- Less than 40% were F even though starting at age 40, the P of HTN in non-Hispanic BF (NHBF) surpasses P in NHBM (50% vs. 40%), P in NHWF nears P in NHWM (23% vs. 25%) and P in Mexican American (MA) F catches up with P of MAM (30%); and at age 60 and above, P in NHWF (68%), NHBF (82%) and MAF (68%) surpasses P in their male counterparts (58%, 77% and 58% respectively).
- Only one sixth was Black even though the age adjusted P of HTN is higher in NHB (34%) compared to NHW (29%) and MA (21%).
- Only one twelfth was Hispanic, Asian or Other.
- Compared to other subpopulations, more Blacks dropped out of studies.

Conclusion: The numbers of women and ethnic minorities enrolled in anti-HTN drugs trials did not adequately represent the P of HTN in these sub-populations. Therefore, findings from a mostly White male population were generalized to these sub-populations. Given the knowledge that Blacks do not respond well to ACE-I and BBs, and the NHANES findings that HTN control rates are lower in women and Mexican Americans, there is need for adequate representation to optimize the chance of discerning differences between the supbpopulations.

Enrollment and Drop-out by Sex and Ethnicity

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<th>Sex</th>
<th>Ethnicity</th>
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<tbody>
<tr>
<td></td>
<td>Males (M)</td>
<td>Females (F)</td>
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<tr>
<td>Enrollment</td>
<td>53,168 (61.7%)</td>
<td>32,969 (38.3%)</td>
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<td>Drop-out</td>
<td>5,819 (10.9%)</td>
<td>3,814 (11.6%)</td>
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