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Clinical trials: Australian prospective view

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The regulatory agencies need to have pro-active approach in handling clinical trials throughout the globe. FDA as well as other regulatory bodies should continue to encourage unbiased gender and race participation in the clinical trials. Australia's National Health and Medical Research Council does ask researchers running trials whether they'll include equal numbers of men and women, but there's little follow up to enforce the guidelines. The sponsors should conduct sex analysis of the subjects enrolled at the clinical trial sites. Prospective design of clinical trials for sex analysis would provide more relevant statistical information. Trust, communication, education, and building a presence within the community are successful means to increasing diversity in clinical trials. Collaborative efforts are essential across all sectors of medical product research and development. Regulatory and review bodies must focus on patients' needs and facilitate the clinical trial process. Phase III trials are not powered to assess trends in subgroups. In order to make an impact, analysis should be done in Phase III, not just post marketing studies. Manufacturers still want to make one-size-fits-all, and also don't want to have to make many different dosages. There is a high prevalence of off-label and unlicensed drug use confirming that it is a widespread phenomenon. It is important for both the marketing authorization holder and national and international regulatory authorities to monitor for any consequential safety concerns and to take appropriate measures to address them, as well as to identify research priorities and mandate clinical studies to resolve important questions. Regulatory authorities should use existing clinical evidence on the use of off-label and unlicensed drugs in decision making and support conducting rigorous clinical trials only when necessary in order to fill the gaps in pediatric pharmacotherapy.

It is recommended to the clinical trial sponsors that researchers use consent forms, promotional materials, and other study forms in age-appropriate formats and adjusted literacy levels. There are many tools and promotional items like large-print, third-to fifth-grade reading level materials, accompanying audiovisuals for the hearing- and vision impaired, and other clinical teaching aids that are appropriate to culture and literacy level (e.g., videos, charts, and diagrams). It's the duty of the Liaison Committee for Medical Education, which addresses education regarding clinical research, amend medical education requirements and curricula objectives to sensitize future practitioners to the special needs of older and elderly clinical trial subjects or volunteers.

There is a need for the regulators, policy makers and the stakeholders to analyze the bitter truth of conducting clinical trials impartially. The stakeholders as well as the clinical trial experts should plan their strategy in age-appropriate formats. Therapeutic good administration (TGA), National health and medical research council (NHMRC) and clinical trial action group (CTAG) Australia should work coherently to develop simplified ethical and legal procedures and constantly monitor the progress of the trials with no age-related barriers. The health care system in Australia has to successfully manage an increasing absolute number of frail older people with multiple co-morbidity and disability.

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