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Drug Approval Regulation in Canada and USA

Since the thalidomide tragedy in the late1950s, there has been a reluctance to include women of childbearing age in clinical trials. However, this fear cannot be used as an excuse to not include females in clinical trials, and, with proper care and regulation, increased female participation has been reached. The United States adopted regulation early on to increase the participation of women, while a new regulation in Europe is going to improve this as well. Here follows an overview of the issue in Canada and in the USA. The third part of this series will deal with new regulation in Europe.

Health Canada Guidance Document

In 2013, Health Canada issued a Guidance document to address the under representation of women in clinical trials. Health Canada argue that ?analysis of clinical trial data by sex may identify clinically relevant sex differences in therapeutic response and, as a result, minimize the risks, maximize benefits and promote the optimal use of therapeutic products in both women and men? (Health Canada, 2013). The Guidance document also includes pregnant and breastfeeding women. As well as this, it recommends that, if data from early phase trials do not indicate potential sex-related differences, it cannot be assumed that clinically relevant differences do not exist. The Guidance document therefore recommends that the statistical section of the study protocol for Phase III trials include pre-specific plans for asserting sex related differences.

The US Food and Drug Administration

The US has been on the forefront of developing policies for including population groups such as women and minorities in biomedical research and clinical studies. Policy drivers have been Congress, the National Institutes of Health (NIH) with its

Office of Research on Women?s (ORWH), as well as the Food and Drug Administration (FDA) and its Office of Women?s Health (OWH), which was established by Congressional mandate in 1994. As far back as 1993, the NIH addressed the exclusion of women from biomedical and clinical studies through the NIH Revitalisation Act that called for women and minorities to be included in all human subject research in adequate numbers to allow for valid analyses in phase III clinical trials. The NIH explicitly stated that cost was not an acceptable reason for excluding women and minorities.

FDA has produced guidelines to ensure that women will be appropriately represented (FDA, 1993). While not mandatory, it amended the previous FDA policy of excluding most women of childbearing age to participate in early phases of clinical trials. The FDA?s Office of Women?s Health advocates for the participation of women in clinical trials, and for sex, gender and subpopulation analysis. It protects and supports the health of women through policy and science. The FDA requires sponsors to include a fair representation of both sexes as participants in clinical trials so that clinically related differences in response can be detected. The guidelines state that sponsors should collect gender-related data during research and development, and analyse the data for gender effects in addition to the other variables of age and race.

FDA Safety and Innovation Act

The FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (2014) sets out important steps for making clinical trial data across the demographic spectrum of sex, race/ethnicity, and age more transparent and publicly available. It reflects the FDA?s commitment to encourage the inclusion and greater representation of a diverse patient population in biomedical research leading to the development of medicinal products to meet the health needs of patients. The Action Plan asks for subgroup data to be analysed, thus

ensuring the safety and effectiveness of the medicinal product in a wider population. The Action Plan includes 27 items for improving the completeness and quality of demographic subgroup data collection, reporting and analysis (quality); identifying barriers to subgroup enrolment in clinical trials and employing strategies to encourage greater participation (participation); and, making demographic subgroup data more available and transparent (transparency).

FDA Drug Trial Snapshots

This is a new programme initiated under the 27-step Action Plan to make demographic subgroup data more widely available. A sample of Snapshots for recently approved products was posted on the FDA website for comment. Starting in 2015, based on the feedback received, FDA has posted a Snapshot for every new medicinal product approved. The Snapshots provide easy to understand information at a glance: including demographic breakdown by sex, age, and ethnicity and providing efficacy and safety results sorted demographically. However, FDA cautions that ?conclusions regarding how effective and safe a drug is among different sex, race, and age groups cannot always be made, often because the numbers of patients in some groups are too limited to allow for meaningful comparisons to other groups and to the overall results? (FDA, 2016). This statement points out one of the major challenges that still need to be tackled.

References

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This project has received funding from the European Union?s Seventh Framework Programme for research, technological development and demonstration under grant agreement no 612236.

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