Novartis Position on Clinical Trials in Developing Countries

The rise of capabilities and education in developing nations has enabled globalization of businesses or activities incl. biopharmaceutical Research & Development. Investments of multinational companies in the developing world contribute to the development of national economies and health care systems, enabling higher standards of quality as well as global access to academic expertise and patient populations. As a result, industry is adapting its clinical trials footprint to the global pattern of disease and availability of ethnically diverse patient pools, as well as responding to emerging markets’ expectation for relevant local clinical trial data.

However, practices in the developing world are frequently scrutinized to ensure they are not used to “escape” high regulatory burden or ethical standards in Europe or the USA. While every country has general ethical and legal standards most developing nations have no specific legislation for this critical part of the R&D value chain.

Novartis Position

Novartis acknowledges that the situation of clinical study participants in developing nations is more complex than for those conducted in the developed world. Novartis strives for the highest possible protection of all study participants and is globally committed to a single set of core principles which governs all studies sponsored by Novartis:

1. All clinical studies, independent of geography, must comply with the same ethical principles to protect the safety and well-being of study subjects. This includes adhering to the ethical values embodied in the Declaration of Helsinki and to international quality standards, including Good Laboratory Practice (GLP), Good Clinical Practice (GCP) guidelines, national regulatory and legal requirements.
2. Clinical studies for innovative medicines and devices are only conducted in countries where there is reasonable expectation that the drug tested will be submitted for marketing authorization and be made available to patients/subjects, once proven safe and efficacious.
3. When selecting clinical research sites, Novartis takes care that the sites are adequate, that researchers as well as health care personnel are experienced and have received appropriate GCP-training. It also ensures an appropriate level of monitoring and oversight by qualified monitors and auditors.
4. When recruiting participants, researchers strive to ensure that no discrimination arises based on economic, gender and/or ethnic factors, while respecting cultural sensitivities and the requirements of the relevant study protocol. Special care will be taken when recruiting trial participants from vulnerable populations, such as children or the economically deprived.
5. Globally valid principles of genuine, voluntary and informed consent to the research must respect local specifics and language. If literacy or comprehension may be of concern, family, community representatives and/or independent witnesses should become involved.

6. The choice of a comparator, i.e. placebo and/or active treatment, will always be justified on both scientific and ethical grounds.

7. Prior to the start of a study all appropriate trial documentation must be reviewed and positively assessed by independent and appropriately constituted ethics committees and, where required, by the relevant health authorities.

8. Where applicable, e.g. in the case of life-saving therapies or serious consequences if the medication was withdrawn, research participants may, after trial completion, be offered participation in an extension study until marketing authorization. The requirements are evidence of the product's efficacy and safety, local regulatory authorities' approval and the informed consent of the research participants.

9. Information and results of Novartis-sponsored clinical trials are posted on relevant public databases in a timely fashion in agreement with relevant legal obligations and the Novartis position on "Disclosure of Clinical Research Information".

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