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Botanical drug development: Right and wrong on clinical studies

Medicinal plants are inexhaustible sources from which many of today's most useful drugs have been developed. While the majority of plant-based drugs are new (single) chemical entities (NCEs), a category of botanical drugs has recently reappeared in the US. Botanical drugs are defined as finished drugs for which the active ingredient is a complex, polymolecular drug substance. Although the criterion of adequate and well-controlled [clinical] studies remains a basis of new drug approval for the United States, botanical products pose unique challenges to clinical development due to their complex nature. This session will describe the clinical development of botanical drugs, with a focus on the US market. It will touch upon the differences between botanicals and NCEs and how these differences impact the types, designs, and even the timeline of clinical studies conducted for US drug development. Through examples, it will also relate some of the hurdles posed by complex botanical drugs which have been experienced in clinical studies of these products-both in research and in regulatory settings.

Biography

Carmen Tamayo, MD directs the Canada Region of Heterogeneity, LLC. She is trained in Internal Medicine at the Central University of Venezuela. After moving to Canada with family, she completed Post-graduate studies in Public Health and Epidemiology at the University of Toronto. Since 1995, she has actively participated in policy and regulatory activities addressing traditional, complementary and alternative medicine (TCAM) research, with the Canadian National Cancer Institute. Her consulting has included government, industry, and nonprofit scientific organizations, including heterogeneity (since 2008), McMaster University Centre for Evidence Based Medicine, and the University of Western Ontario School of Medicine and Dentistry at the University of Western Ontario. For Health Canada's Natural Health Products (NHP) Directorate, she served as Clinical Trial Project Coordinator for product review and assessment, collaborating in the agency's development of a framework for NHP clinical trials. She has chaired and directed numerous programs and workshops as a member of the Drug Information Association (DIA), the International Pharmaceutical Federation (FIP), and the Latin American Phytomedicine Society (Sociedad Latinoamericana de Fitomedicina). She also serves as an expert reviewer for the World Health Organization and other international committees and several CAM and Phytotherapy journals, and is a past Co-editor of the *Journal of Integrative and Complementary Medicine (JICM)* – An international forum for evidence-based practices.

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