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RESEARCH ARTICLE

THE HUMAN GUT MICROBIOME: CONSIDERATIONS TOWARD REGULATORY TESTING FOR DRUGS AND VACCINES

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Abstract

Health regulatory authorities worldwide are tasked with approving drugs, medical devices, and vaccines to ensure their safety, efficacy, and quality for public use. Significantly over the past three decades, testing of these products has witnessed increasingly stringent tests due to advancing scientific knowledge and technology. Specifically, the relatively new field of studies on the human gut microbiome and its interactions with drugs and vaccines may accumulate enough evidence in the future to justify its testing prior to regulatory approval or during post-marketing surveillance.

Introduction:-

Throughout the ongoing pandemic, new and innovated drugs, medical devices, and vaccines have been developed rapidly in efforts to control the spread of SARS-CoV-2 and to treat COVID-19. These and all other products of clinical research and development (R&D) undergo stringent testing and trials before regulatory authorities can approve of their safety, efficacy, and overall quality. Foremost among guidelines for researchers and manufacturers include those from the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the World Health Organization's Pre-Qualification Program (WHO PQP), and the International Standards Organisation (ISO).A quality assessment kit, the Global Pharma Health Fund Ev Minilab (GPHF), further assesses post-regulatory approvals with significant findings on the need for improvement of testing in certain regions across the globe.[1]As knowledge and experience continue to accumulate over decades, tests have been added gradually in order to better safeguard the public. For example, the ICH released Efficacy guideline E5 (Revision 1) in 1998 which asserts on ethnic factors to consider in accepting foreign clinical data.[2] Such factors embrace culture, diet, geography, medical practice, race, and so on. Because of recent science that has studied the impact of such factors, disease, and pharmaceuticals on the natural gut microbiome, further relevant R&D tests concerning the microbiome could similarly be recommended in the future.

In the medical sphere, the gut microbiome is known to be influenced by factors such as diet and disease and consists of commensal microorganisms that function to maintain homeostasis, involving maturation of the immune system,[3] not only within the intestines but also beyond, as far as the human brain.[4]Even the environment impacts the gut microbiome. In Zimbabwe, the protection of rotavirus vaccine in infants has been significantly multiplied after water, sanitation, and hygiene (WASH).[5]In a number of other studies, not only infections but also chronic diseases including cancer, cardiovascular pathologies, diabetes, and obesity have been observed to harbour altered microbiomes.[6] Clinical uses of the gut microbiome have thus been approached, such as restoring the microbiota through low-calorie high-fiber diets, characterizing individual microbiomes for precision medicine, and sourcing potential therapeutic treatments,[7]including alternatives to antimicrobials.[8]However, studies have also revealed that some changes to a healthy microbiome may be due to interactions with pharmaceutical molecules.[9] While many antimicrobials and other drugs have successfully targeted specific sites as causes of disease, research has hinted at

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possible cases of long-term consequences to the gut microbiome, which in turn can affect other systems, notably the immune system and its response to vaccines.[10]In this regard, based on persevering microbiome research, microbiome safety and quality tests may be indicated in the future, either prior to regulatory approval or at least during post-marketing surveillance.

Fortunately, tools are now available to analyse this microbiome in detail, in particular next-generation sequencing (NGS), third-generation technology, bioinformatics, and microbiome platforms.[11]Although recent expert discussions have concluded that it is difficult to establish what constitutes a "healthy microbiome",[12] moving forward, upcoming studies can advance our knowledge of both positive and negative effects of medicines and on vaccines being welcomed during this pandemic. The resulting evidence base can then promote guidelines on additional quality tests for their regulatory approval toward heightened safety of mankind.

Disclosure:
The author reports no conflicts of interest in this work.

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