PRI Clinical Studies Task Group

A task group dedicated to supporting the development of microbiome-based drug products by addressing the key challenges that this new type of drug represents when designing robust clinical trials.

A significant challenge in the microbiome and health industry is the conception of robust clinical trials which can allow for the demonstration of efficacy and safety of microbiome-based drug products.
Such a robust demonstration is of the utmost importance for patients as well as for industry in order to avoid the multiplication of trials which are not only costly but could also be considered as unethical if designs do not allow robust assessment of the benefit/risk ratio. Above all drug products, microbiome-based medicinal product designs are particularly sensitive to bias due to the high level of influence of environmental factors.

Over the last 9 years, the PRI, a non-profit, pro-industry, European association has supported its members in their efforts to navigate the current pharmaceutical EU regulatory framework in order to develop and register this new type of drug product.

Today, as developments are moving along, more companies are reaching the clinical trials phases and particular challenges have begun to emerge at this level for microbiome-based products. Failure to demonstrate efficacy seems to be heavily related to the specific nature of these products and its large influence on clinical trial designs. Competent authorities have expressed at multiple occasions their feeling that the clinical trials designed are not completely up to their expectations, which then makes their assessment of the efficacy and safety of the products difficult.
Therefore, within the Good Clinical Practices framework, multiples factors are to be considered when it comes to the design of robust clinical trials for microbiome-based products.

The PRI is now tackling this issue by trying to bring together developers, CROs, and any other stakeholder potentially involved in this particular discussion, in order to define the best approach when it comes to the basis of their interaction and their respective needs and constraints regarding the optimization of clinical trial designs.
The Task Group will also address the particular sensitivity of the designs to environmental factors when it comes to the demonstration of safety and efficacy of microbiome-based products.

The PRI Clinical Studies Task Group is looking at providing insight to the industry regarding:

- The development of an appropriate Target Product Profile in order to optimize all phases of development including clinical trials
- The key bias often encountered in clinical trials for microbiome-based drug products and how to overcome this challenge
- The preliminary necessary due diligence to be done by a developer before entering into collaboration with a CRO for the clinical trial phase
- The constraints and needs of CROs in order to optimize the design and realization of such trials

For more information about this or any other Task Group coordinated by the PRI, please contact:

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