Session 3 – Quality Standards for Challenge Strains

Requirements for challenge strains for Clinical Trial Applications and Marketing Authorization Applications

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Human challenge studies are known since almost a century to serve as good models to investigate the pathology of aetiological agents as well as the mode of action of vaccines and therapeutic products directed against a wide range of infectious agents.

While these efforts are still largely considered as proof of concept or supportive information generated in a very early phase of drug or vaccine development, innovative programs aimed at accelerating availability of new vaccines and therapeutic products, while in parallel lowering the overall development costs, have identified human challenge studies as a valuable tool to achieve both goals. Furthermore, many regulatory authorities around the world are in the process to develop guidelines to define generally accepted standards aimed at upgrading human challenge studies to a scientific and regulatory level allowing use of study results as an essential part of the clinical development program supporting licensure rather than considering them as being investigational only. While WHO has perfectly set the scene by recently publishing a guidance document named “Human Challenge Trials for Vaccine Development: Regulatory Considerations”, serving as a general framework for conducting these studies and taking advantage of the study results most effectively, no specific guidance is available describing what type of information would be required, e.g. for approving human challenge studies following a clinical trial application (CTA) or for ensuring validity of these studies when used in a Marketing Authorization Application (MAA) dossier. Although microbial or viral challenge strains cannot be considered as investigational medicinal products (IMP) in sensu stricto, many scientific and regulatory requirements applying for vaccine IMPs would also apply for challenge strains. As such, this presentation exemplifies in detail which information relevant to the challenge strains should be provided in order to comply with scientific, legal and regulatory provisions relevant to the Common Technical Document (CTD) and the EU Investigational Medicinal Product Dossier (IMPD).