OPEN ACCESS Freely available online

Journal of Clinical Trials

Editorial

Human Clinical Trials with Vaccines

John P *

Cancer Research UK Clinical Trials Unit, University of Birmingham, USA

SUMMARY

Vaccines have a long history of excellent safety and a highly positive benefit/risk profile. Even so, the lack of specific guidance from regulatory agencies specifically relating to the first application of a new experimental vaccine in humans has hampered product development. Most of the regulatory guidance documents for manufacturers are too broad and sometimes only vague where vaccines are concerned. As regulators deeply involved both in the development of the European Medicines Agency's (EMA; London) new regulatory framework on risk identification and mitigation, and in assessment and authorization of clinical trial applications for biotechnological and biological products (especially vaccines), we have been repeatedly approached by companies and vaccine developers regarding regulatory issues for first-in-human clinical trials. Here, we discuss these considerations as they relate to vaccines.

EMA guideline for risk identification and mitigation for first-in-human clinical trials based on the apparently considerable uncertainty among developers. We describe how regulators apply the guideline and where we see the limitations or the need to take alternative approaches. The discussion primarily focuses on prophylactic and therapeutic vaccines against infectious diseases as this classic field of products is associated with particular uncertainty.

QUALITY/CMC CONSIDERATIONS

At the time the step from animals to humans is made in drug potency bacterial or viral antigens in the vaccine should be given special attention as this is a crucial factor to mediate.

NONCLINICAL CONSIDERATIONS

Although animals present 'good models' for a variety of human physiological functions, they also have significant limitations when it comes to species-specific aspects; diseases induced by infectious agents relevant to humans may not exist in animals or may cause different symptoms.

CONCLUSION

Most vaccines have an excellent safety record. As vaccination against infectious diseases contributes hugely to public and individual health all over the world, one needs to exercise caution when discussing risks associated with vaccines so as to avoid false and misleading signals for the public and politicians. Such a balanced view is particularly important with the emergence of new infectious agents.

Correspondence to: John Perry, Cancer Research UK Clinical Trials Unit, University of Birmingham, USA, E-mail: johnperry@martin.com

Received date: October 26, 2020; **Accepted date:** November 11, 2020; **Published date:** November 19, 2020

Citation: John P (2020) Human Clinical Trials with Vaccines. J Clin Trials. S8:e002