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Evidence supporting efficacy: The good laboratory practices orphan

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The high failure rate (85-95%) for drugs and biologics during clinical testing is continuing to contribute to a steady decline in investment dollars for early stage development and inflation in overall development costs. The major reason for failure is not safety but rather failure to meet efficacy endpoints during clinical testing. A root cause is the poor quality of nonclinical studies supporting efficacy based on systematic reviews and high rate of failure (>75%) of pharma to reproduce published results. Regulatory guidance has established standards for toxicology/safety data derived from nonclinical testing including the requirement that key toxicology studies are performed in accordance with good laboratory practices (GLPs). Nonclinical data supporting the efficacy of a candidate therapeutic is treated as a GLP orphan. Ironically, these data are often the foundation upon which biotech companies or development programs are established, yet the first time efficacy is subjected to rigorous evaluation is in phase 2 clinical testing where failure can have devastating consequences. The state of affairs with nonclinical studies has been characterized as being equivalent to where clinical trials were half a century ago. We cannot test hypotheses regarding the basis for these failures until the studies are consistently designed, performed and reported according to gold standards/practices approaching that of clinical trials. This presentation will discuss the impact of high failure rates, root causes and steps that can be taken to mitigate failures. This presentation is important to all stakeholders including entrepreneurs, scientists, management and investors.

Biography

L. Bruce Pearce received his undergraduate training in Chemistry and Biology at the University of Massachusetts and doctoral training in Pharmacology at the State University of New York. He completed postdoctoral training within the Departments of Pharmacology at Yale School and Harvard Medical School. He has worked for >25 years in academia and industry and is currently Senior Consultant at Biologics Consulting Group. Drug development experience includes entrepreneurial ventures, oversight of pharmacology, toxicology, pharmacokinetic and physiologic research. Current research interests include preclinical and clinical study design, risk/benefit analysis, translational pharmacology and decision making in drug development.

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