Psychology
Research Seminar Programme

SCHOOL OF NATURAL SCIENCES | UNIVERSITY OF STIRLING

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Animal Research in Biopharmaceutical R&D, the Good, the Bad and the Ugly -

Impact of Good Statistical Practice

Abstract

Biopharmaceutical Research and Development (R&D) faces several unprecedented challenges and is under growing pressure from loss of revenue arising from patent expirations, more demanding regulatory requirements, increasing unmet medical needs, cost-constrained healthcare providers and increasing and unsustainable R&D costs. Not all of these challenges are new to the industry. R&D productivity trends have been moving downwards for over a decade and at best have recently reached a plateau. With increasing costs and low probability of success, especially in the earlier phases, business as usual is no longer an option. We briefly consider the future likely restructuring of Biopharmaceutical R&D, opportunities this affords to Universities, Biotechs, and SMEs and the critical role of animal experiments in bringing new medicines to patients

Whatever new business models emerge from restructuring a major factor contributing to high failure rates for early clinical proof of concept studies is insufficient robustness in the pre-clinical studies and flawed pre-clinical research in which the use and outcome of animal models is pivotal in translation from bench to bedside. Statisticians make a critical contribution to drug hunting both in the 'Discover' and 'Implement' phases. In the early clinical phases of development Statisticians input into several key steps: determination of effective dosing levels and schedules, tolerability and safety of drugs, as well as how the treatment compares with alternatives in terms of benefits, risks and likelihood of reimbursement. It is widely accepted that it is not possible to answer these questions in the clinical setting without utilizing expert statistical input from both regulators and drug developers. In the Discovery phases there is no regulatory mandate for involvement of Statisticians. Why is it considered appropriate to conduct pre-clinical studies without insisting on the same level or statistical rigour and quality? Good design of studies, execution, analysis, interpretation and reporting of results, both positive and negative, will help make pre-clinical experiments more reproducible. In the United States, it is estimated that upwards of 0.5 billion animals are used in biomedical research each year. Despite strenuous efforts in the United Kingdom to reduce the number of animals used in research, this has not been sustained. In AstraZeneca we believe we have an ethical and scientific obligation to improve the quality of pre-clinical animal studies, ensuring that where they are used, they include as few animals as possible and are run in a way that provides reproducible and valid information. We present several case studies across different therapy areas, highlighting improvement opportunities in the design, conduct and analysis of animal studies. We conclude with an overview of a systematic review of all AstraZeneca animal studies in an 18 month period and highlight lessons learned and next steps.

Seminars are free of charge and held on

Thursdays @ 4:00 pm Room 3A94

Refreshments are served upon arrival * All are welcome

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