X|ZEN|CIS

Translational Safety Solutions

INTEGRATED PRE-CLINICAL & CLINICAL SERVICES FOR THE PHARMACEUTICAL INDUSTRY

Our integrated approach to translational safety

Innovative pharmaceutical product development is a highly competitive, expensive and risky business. Many failures and attritions relate to inadequate safety. Nevertheless, few companies follow an integrated, incremental safety strategy with defined objectives along the pre-clinical and clinical safety value chain. Much is left to good faith and regulatory compliance alone.

The approach to Safety is often poorly structured in the industry. Protracted R&D timelines spread the accountability for safety to different functional entities, notably Nonclinical Drug Safety and Clinical Patient Safety/ Pharmacovigilance. However, the safety profile of a candidate drug requires the integration of data and information from sources well beyond these functional entities – a concept literally every development program in the industry is struggling with. There are no formal roles assigned to this task.

The value and opportunities of an integrative, proactive approach to Safety, executed as a parallel, objective-driven development of therapeutic efficacy and safety claims, are indisputable. Safety claims are more compelling, unavoidable safety attritions happen at the earliest point in time, and control over an asset's safety is retained.

The safety profile of a pharmaceutical product is made, not revealed!
Safety risks must be assessed and mitigated, not taken!

The thalidomide derivative and blockbuster drug lenalidomide (e.g., revlimid) is a prototypical execution of the above two statements – a textbook example of Safety Product Development resulting in the 3rd best-selling product in the world.

We are here to help our clients along this path. Our expertise spans the entire R&D value chain, from early Drug Discovery over Clinical Drug Safety/ Pharmacovigilance to marketed product support and licensing. We can develop proactive, forward-looking safety strategies according to defined objectives. We can process safety problems in clinical development and for marketed products and develop solutions and mitigating strategies. We also support inbound and outbound licensing activities and support investors with concise asset evaluations and integration of results in formal valuation procedures,

In everything we do, we select and integrate information and data from all relevant sources – never just from Non-clinical or Clinical Drug Safety alone. We recently published our unique approach to pharmaceutical drug safety in chapters 22 and 23 of Principles of Translational Science in Medicine From Bench to Bedside 3rd Edition - July 15, 2021.

We are not confined or committed to any specific Therapy Area, type of pharmacological modulators, therapeutic concepts or life-cycle stage. We review each opportunity carefully before making any

commitments. Should we not feel 100%confident, we will say so and do our best to identify the most appropriate party for the task - free of charge.

Xzencis is represented by Dr. Steffen Ernst. However, many assignment require additional hands, brains and expertise. Xzencis is well connected and can draw on an extensive network of senior, experienced Toxicologists, NCDS sub-discipline experts, Safety Physicians, Safety Scientists and Pharmacovigilance Systems experts - all with tested and proven, impeccable track records.

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