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INTERNATIONAL DISCOVERY SERVICES & CONSULTING

Pharmacum Nuntius:

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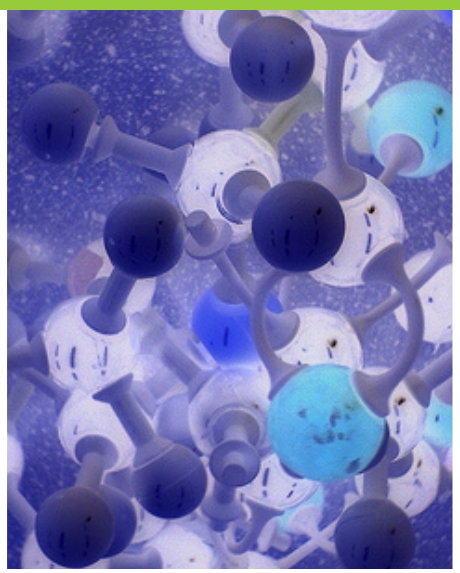
As you are winding down for the day and sit down to read we bring you a mix of interesting articles spanning commercial assessment, oncology clinical trial review, clinical CROs, and the latest marked drugs for melanoma. Enjoy!

Mark Creswell, CEO



Phase I, II, and III Oncology Clinical Trial Design: A Review of Statistical Considerations

This is nicely thought out review article by Ananthakrishnan and Menon summarizing the design of oncology clinical trials. The abstract of the article states: "Cancer is a disease that occurs due to the uncontrolled multiplication of cells that invade nearby tissues and can spread to other parts of the body. An increased incidence of cancer in the world has led to an increase in oncology research and in the number of oncology trials. Well designed oncology clinical trials are a key part of developing effective anti-cancer drugs. This review focuses on statistical considerations in the design and analysis of oncology clinical trials." Click here for the full article.

CROs: Slowly Shifting to Adaptive Clinical Trial Designs

Zachary Brennan in his article on adaptive trial design notes that adoption of these few practices has been slow among CROs. The expectation is that this will improve and increase over time. Adaptive trial designs are becoming more widely adopted, accepted, and valued especially in the early stages of clinical development. Adaptive trial design has the potential to save companies money and time in particular if early termination can be achieved when the product has little hope of success. Click here to view the article.

Commercial Assessment and Valuation: A White Paper

Whether we like it or not, much of drug discovery and development is a for profit activity. Investors, from VCs to big pharma, are looking to improve the lives of patients while maximizing the return on their investment. Jeff Simpson writes in his white paper how even the smallest company can have an effective valuation of their product or products. These valuations are used in negotiations with potential partners and investors and as part of the decision to advance a product into development. Click here to view Jeff's white paper.

Two new drugs approved for Melanoma:

GSKs new metastatic melanoma drugs Mekinist® (trametinib) and Tafinlar® (dabrafenib) are both "kinase inhibitors indicated for the treatment of patients with unresectable or metastatic melanoma" with BRAF V600E or V600K mutations in the case of Mekinist and BRAF V600E mutations in the case of Tafinlar "as detected by an FDA-approved test."

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A Spotlight on IDSC's Director...Jeff Simpson: Commercial Assessment & Valuation

A skilled marketing and sales executive with proven accomplishments at The Upjohn Company, Pharmacia and Pfizer, Jeff advises biotech and pharmaceutical companies on business development, commercialization strategies, product assessments and valuations, portfolio planning, lifecycle planning, advisory boards, competitive intelligence, and launch planning for new products, indications and formulations, for both the US and non-US markets. During his 29 years in the pharmaceutical industry, Jeff's commercialization experience includes products for psychiatry, neurology, pain management, sleep disorders, womens health, infectious diseases, inflammation, metabolic diseases, urology, immunology, and dermatology. More...

FROM HIT TO THE CLINIC: IDSC IS YOUR DRUG DISCOVERY & DEVELOPMENT PARTNER