



# IDDI

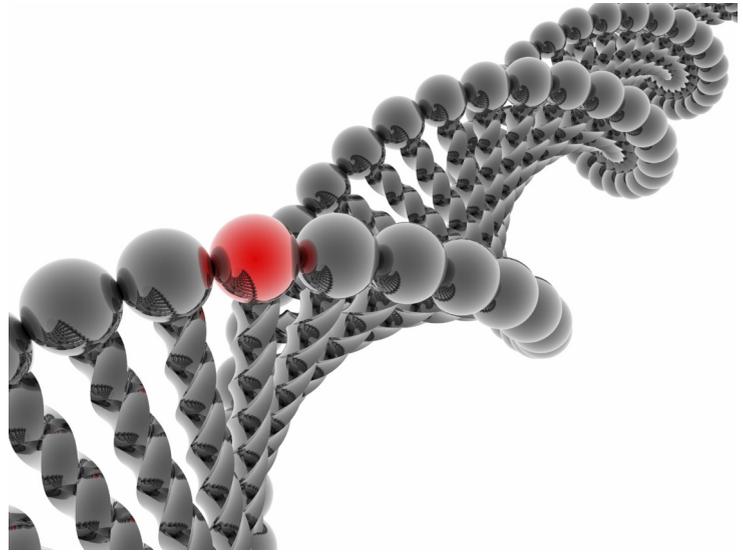
## Expert provider in eClinical and Biostatistical Services

With a staff of 65 collaborators and a planned turnover of €7.3 M in 2011 (90% from exports), IDDI combines expert methodology and innovative technology to optimize the design and conduct of clinical trials from phase I to IV. The company is reaching out to foreign markets through major collaborations in Asia and the US.

**E**stablished in 1991 and based in Louvain-la-Neuve since 2006, IDDI (International Drug Development Institute) has increased its turnover from €6 M to €7.3 M in one year and gained more than 20 new clients in 2011. The dynamic development of the group is based on a niche positioning in the fields of biostatistics, data management and central randomization. IDDI also provides biostatistical support for the design of trial protocols and acts as an expert for interactions with regulatory agencies (EMA, FDA).

IDDI's success stories reflect the group's dynamism. In the early 2000s, IDDI advised a US biotech planning to enter into Phase II to perform 2 combined Phase II/III trials in order to test for different doses. As a result, one year was saved in the successful submission procedure of this new ophthalmic drug to FDA and EMA. More recently, IDDI advised a French biotech to adopt a Bayesian design and a seamless transition between Phase II and III, using a biomarker to better select patients who benefit from treatment. This innovative approach was approved by FDA. IDDI helped an ophthalmology company to switch from paper CRFs to EDC in five weeks using a hybrid DM system in order to ease and speed up clinical operations. The group also contributed to the validation of prognostic and predictive biomarkers in breast and colon cancer.

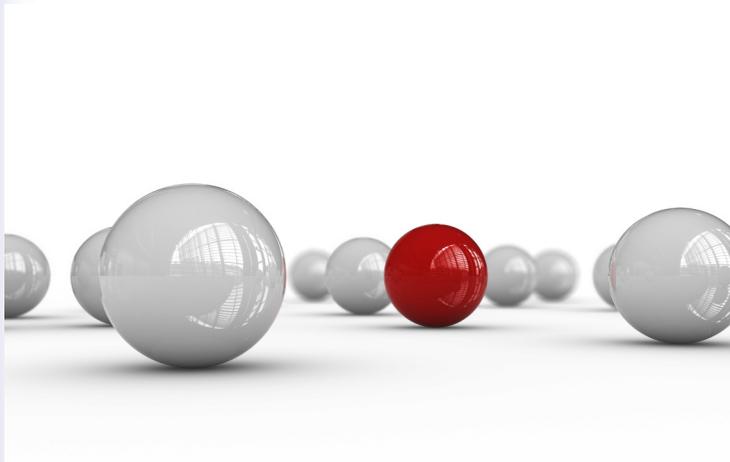
These success stories have enabled IDDI to develop strategic collaborations with leading biotechnology companies worldwide. For instance, IDDI supports the central randomization and EDC support for a leading US biotech company in 5 large Phase II and III trials in hepatitis. Early this year, IDDI has offered its expertise in biostatistics and randomization to a small Chinese biotech company for the assessment of a promising compound in the treatment of liver cancer. IDDI helped another new client, active in the field of prostate cancer, to overcome complex biostatistical issues in phase II and III trials.



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The group has also developed thriving academic collaborations in Asia. In Japan, it is contributing to the meta-analyses of randomized trials in colorectal cancer led by Prof. J. Sakamoto of Nagoya University, and of randomized trials in gastric cancer led by the GASTRIC worldwide collaboration, which includes eight Universities in Japan and Seoul National University College of Medicine in Korea. Over the last ten years, IDDI has offered regular seminars, lectures and classes on statistical issues in clinical development. Entitled "Design and analysis of clinical trials for predictive medicine", the next lecture is planned in August 2012 during the 26<sup>th</sup> International Biometric Conference that will take place in Kobe (Japan). In India, IDDI has offered classes at the Tata Memorial Hospital in Mumbai and is reviewing trial protocols for ICON (Indian Co-Operative Network). In South Korea, IDDI has recently signed a memorandum of understanding to create a long-term partnership with a Korean company that aims at becoming a world leader in biosimilars from 2013 onwards.

IDDI is closely collaborating with 2 prestigious North-American academic groups: TRIO (Translational research in Oncology), supporting 10 major oncology trials, and NSABP (National Surgical Adjuvant Breast and Bowel Project), for which it has an exclusive collaboration agreement to support their Phase II trials.



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