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## InnoMed PredTox Presents Analysis Results from Systems Toxicology Studies

During the latest meeting of the consortium in Antwerp on Jan. 14th and 15th, hosted by J&J, the InnoMed PredTox project reached another critical milestone of the project. Representatives of the sixteen study sponsors, corresponding to the participating pharma companies, presented the Integrated Study Reports for their respective compound studies.

In October 2005 InnoMed PredTox was launched with the goal to assess the value of combining results from -omics technologies together with the results from conventional toxicology methods for more informed decision-making in preclinical safety evaluation. The first two years of the project witnessed the development of consortium-wide procedural and experimental standards as well as animal toxicity studies and subsequent data generation. Now, within the first few months of the third and final project year, the collection of experiment data and data analysis for the individual compound studies are being completed. All consortium data have been centrally processed and stored in a dedicated database, developed by Genedata for the purpose of this project.

The Integrated Study Reports represent the most visible deliverable from this first analysis phase and serve a double purpose. The first purpose is to summarize the results of the analyses from the in-life observations during the individual initial 14 days repeated dosing experiments using both traditional toxicological endpoints and highly multiplexed molecular assays for transcriptomics, proteomics and metabonomics across key samples (liver and kidney tissue, blood and urine).

What differentiates InnoMed PredTox from other initiatives in this area is that the initial studies were designed from the start to support analysis and result interpretation across the traditionally separate domains. Accordingly, the second purpose of the Integrated Summary Reports is to provide the systematic combined analysis and interpretation of all available data for each study. This “systems approach” to toxicology led to mechanistic “Mode of Action” models of the different liver and/or kidney toxicants that were discussed during the Antwerp meeting.



Participants of the 9th project meeting of InnoMed PredTox in Antwerp

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The remaining work will refine and aim to generalize the proposed models by extending the data analysis across the individual studies. The integrated analysis approach naturally requires specific domain knowledge that is provided by experimenters, toxicologists and biologists from the participating pharma and academic partners, and data analysis experts from Genedata. Based on the gross pathologies found in response to the different treatments, three Expert Working Groups have been formed.



The leaders of the newly formed Expert Working Groups during one of the breaks (left to right): Eric Boitier (Sanofi-Aventis), Heidrun Ellinger-Ziegelbauer (Bayer-Schering Pharma) and Katja Arnold (Boehringer Ingelheim)

Under the leadership of Eric Boitier (Sanofi-Aventis), Heidrun Ellinger-Ziegelbauer (Bayer-Schering Pharma) and Katja Arnold (Boehringer Ingelheim) the groups will initially focus on those studies where animals showed signs of liver hypertrophy, bile duct damage or hepatocyte necrosis, and kidney damages, respectively. Results will be presented during the upcoming annual meeting of the American Society of Toxicology (SOT) in March.

**InnoMed PredTox** aims at reducing a key bottleneck in the R&D process namely the assessment of drug safety before new drugs enter the market. It has secured €8 million of budget over 40 months partly funded by the European Commission Life Sciences, Genomics and Biotechnology for Health Priority (LSHB-CT-2005-518170). The project is coordinated by the European Federation of Pharmaceutical Industries and Associations (EFPIA), a body representing the research-based pharmaceutical industry and biotech SMEs operating in Europe. The members in the consortium include: Bayer Schering Pharma, Boehringer Ingelheim, F. Hoffmann-La Roche, Johnson & Johnson Pharmaceutical R & D, Lilly S.A., Merck KGaA, MerckSerono, Nycomed, Novo Nordisk A/S, DK, Novartis, Organon, Sanofi-Aventis (Germany, France), Servier, the Universities of Dublin, Hacettepe and Würzburg, as well as Bio-Rad and Genedata.

For more information, visit [www.innomed-predtox.com](http://www.innomed-predtox.com).

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#### Disclaimer

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