

- ▶ **Arlenda** is a Spin-off from the University of Liège, created in 2003 by a team of experts in statistical and pharmaceutical sciences
- ▶ Drug Development experience:
 - ▶ 20 years in the pharmaceutical industry
 - ▶ Large number of trials
 - ▶ Small molecules and mabs
 - ▶ Expertise in several indications
 - ▶ Phase I and Phase II trials
 - ▶ Bioequivalence to adaptive designs
 - ▶ Discovery to CMC
- ▶ Multidisciplinary knowledge:
 - ▶ PhDs in (Bayesian) statistics
 - ▶ PhD in Pharmaceutical Sciences
 - ▶ Ir in Chemistry and IT
- ▶ Programming expertise:
 - ▶ SAS, Jmp, R
 - ▶ WinBUGS, Blackbox
 - ▶ Java, C++
 - ▶ NONMEM
- ▶ Collaborations with universities:
 - ▶ MSc and PhD student supervision
 - ▶ Involved in Academic research



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Arlenda, modeling **your** drug development

- ▶ **Arlenda** is a company specialized in **Applied « Modeling & Statistics »** for informed and timely decision making in Life Sciences
- ▶ Our consulting services cover the areas of **Early Clinical Phases, Non-Clinical Development** and **specialized software development**
- ▶ **Arlenda** offers **integrated** solutions: services | programs | software | training

SERVICES FOR NON-CLINICAL DEVELOPMENT

- ▶ **Statistics for (bio)analytical methods:** design and analysis of validation, transfer, stability and robustness studies:
 - ▶ Advice in results interpretation and decision-making
 - ▶ Help in implementing methods based on the total error approach and tolerance intervals
- ▶ **Quality by Design:** contribution to the practical implementation of the QbD concept by developing robust optimized processes and methods
- ▶ **Design Space for processes and methods:** determination of the region of reliable robustness for the future performance of a process/method
- ▶ **Biomarkers validation:** design, analysis and report of biomarker studies, including detection screening, diagnosis, prognosis and treatment selection.

CONSULTING SERVICES

- ▶ Wide variety of statistical services from **classical** design and report to **advanced** PK-PD models and simulations in adult and pediatric population
- ▶ Covers the area of **clinical studies, manufacturing** and **laboratories**
- ▶ Three key features: **on-time delivery, quality** and **applied**
You will always be provided with practical and effective solutions: a protocol, programs or even custom software
- ▶ Statistics is the only scientific function that covers drugs from discovery to production
Arlenda helps you to take advantage of statistics by gathering the information available and converting it into added value

Having a global perspective of the data in drug development allows having a global impact on success

SERVICES FOR CLINICAL DEVELOPMENT

- ▶ **Statistics for clinical studies:** writing of the protocol, the statistical analysis plan and the clinical study report, following GCP requirements
- ▶ **Programming** of Tables/Figures/Listings for clinical reports with full QC
- ▶ **Pharmacokinetics/Pharmacodynamics:** from non-compartmental analysis to complex PK/PD modeling, including development of specific analysis plans and reports
- ▶ **Applied Model based Drug Development:** advices in MBDD strategy and implementation for better data analysis and study design resulting in more informed decision making
- ▶ **Effective translational sciences:** optimal leveraging of all the available information, from laboratories, clinic, production,... to improve result predictions and probability of success
- ▶ **Clinical trials simulation and prediction:** programs and advice for the optimal design of studies with appropriate dose-response models
- ▶ **Adaptive designs and optimal designs:** advice in the set-up, conduct, programming and analysis of your design