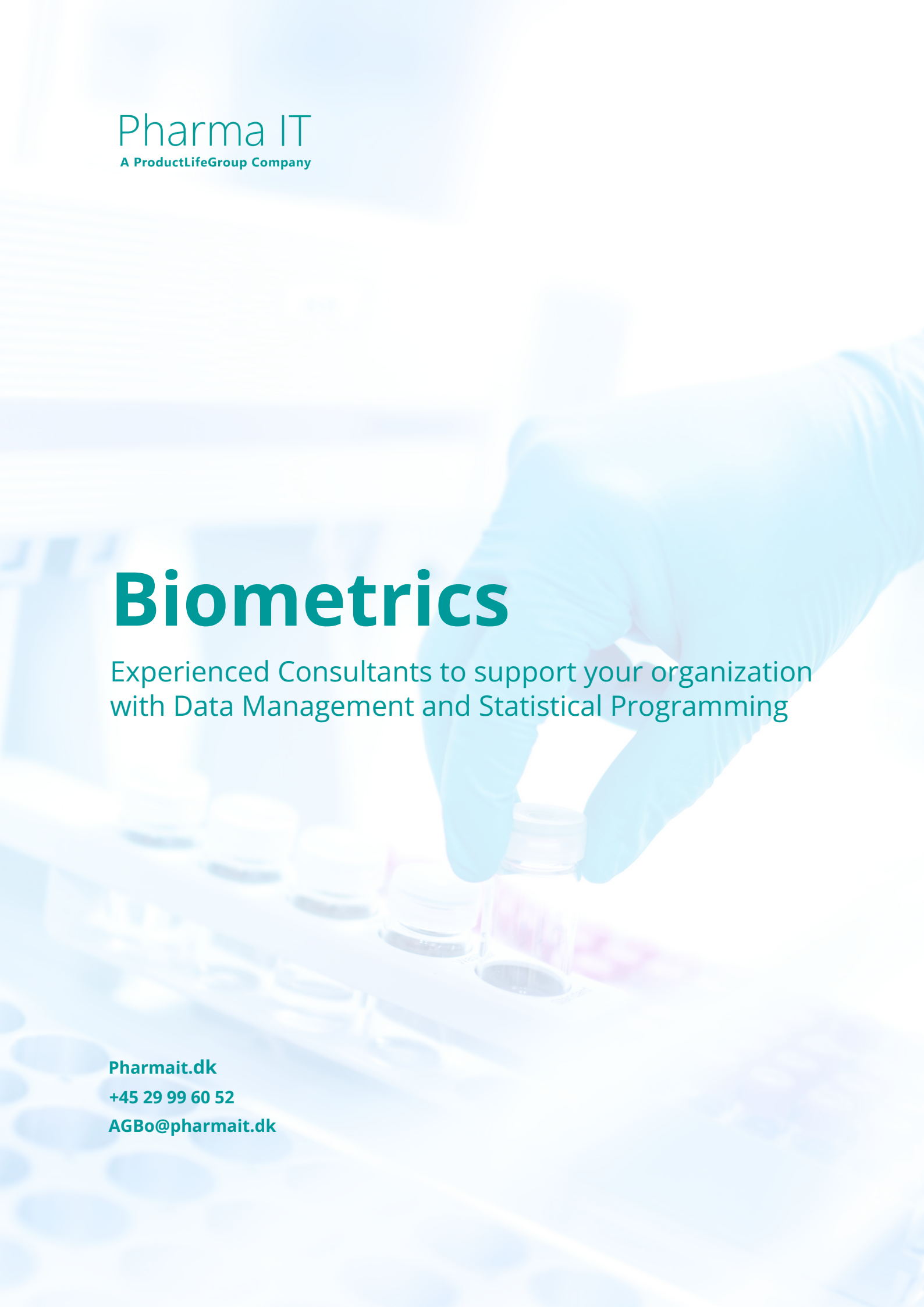
Pharma IT
A ProductLifeGroup Company

Biometrics

Experienced Consultants to support your organization with Data Management and Statistical Programming



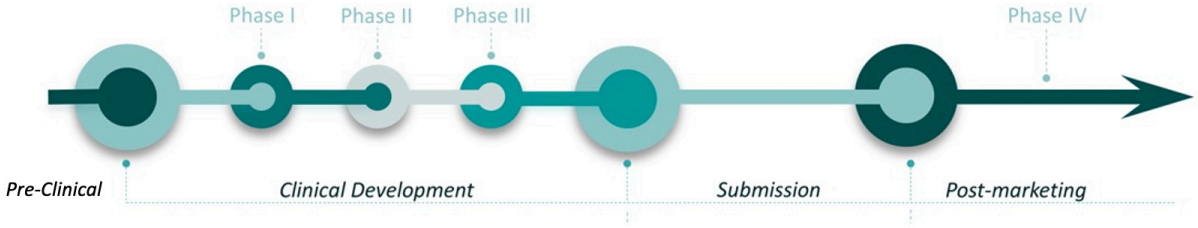
Pharmait.dk
+45 29 99 60 52
AGBo@pharmait.dk

We help you ensure consistent and reliable data for submission

Pharma IT's senior consultants hold vast experience from previous pharma and biotech roles – supporting all phases of clinical trials. We take ownership of our work, with a focus on accuracy and reliability. When you work with Pharma IT you can rest assured knowing our qualified experts can support your organization and ensure consistent and reliable data for submission fully compliant with applicable laws, regulations, and guidelines.

Anni Gatten Boserup
Director of Biometrics & Principal Data Manager

At Pharma IT, we focus on providing experienced consultants that provide extraordinary service quality based in extensive industry expertise:



Data Management (DM)

- Sponsor Oversight covering DM activities from set up to trial closure
- Protocol review & input
- eCRF Design
- Data standardization, data review, data validation, and data reconciliation
- External vendor collaboration
- Database Lock activities and DM documentation
- External data transfer and data flow documentation

Statistical Programming

- Development, validation, and documentation of SAS programs
- CDISC/SDTM/ADAM data standards and TFL's validation
- Development and validation for submission packages
- Documentation of Annotated Case Report Form (ACRF)
- Define.xml's and Reviewers guide (SDRG/ADRG)
- CRO Oversight of programming activities, including contract negotiations
- Data anonymization, de-identification, and Data Sharing procedures

We also offer **Functional Support**, including cross functional work with other Pharma IT consultants in the following areas:

- URL Implementation and System Validation support
- Clinical Operations
- Medical Writing
- Trial Master File set-up and maintenance
- Audit/Inspection preparation
- Drug Safety
- Clinical SOP development
- ClinicalTrial.gov Trial reporting

Need assistance? Please reach out to discuss how we can support your project.

Selected Biometrics Team Profiles

Anni Gatten Boserup
Principal Pharma Consultant with 20 years of experience in the pharmaceutical industry working with clinical data and project management phase I-IV. Experience from international projects and with planning, running and managing data from setup to trial closure. Project management and oversight of DM teams, vendors, internal stakeholders, and mentoring data managers. Process improvement projects to optimize accuracy of data, process simplification and carry over effect between trials and projects.

Daniel Ourstrup
Principal Pharma Consultant with more than 8 years experience from the pharmaceutical industry, working with clinical data and project management in phase I-III trials, quality control, data analysis and customer complaints on drugs and medical devices. Experience with Data Management activities from trial setup to closure, project management and oversight ofDM teams, external vendors, ePROs, eSAE setup and mentoring junior data managers. Furthermore, experience with data management related business projects e.g. Medidata RAVE URL incl. core configurations and Ryze MDR implementations.

Santo Xavier
Principal Pharma Consultant with 17 years of experience in clinical data analysis. Has worked in the pharmaceutical industry for the last 7 years, focusing on clinical SAS programming, data standardization, anonymization and sharing, CRO oversight, and biometrics contract management. Certified Project Manager. Skilled in programming and validating SDTM, ADaM, and submission packages, ensuring compliance with CDISC, PHUSE, and FDA guidelines. Extensive experience in multiple indications, particularly in key disease areas such as oncology, kidney transplant, skin, and brain diseases, across phases I, II, and III.

Do you want to get in touch?

Call **Anni Gatten Boserup** at **+45 29 99 60 52**

or write an email to ***AGBo@pharmait.dk***

We look forward to hearing from you!

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