PERSONAL INFORMATION

Jean-Marc Ferran

WORK EXPERIENCE

2010 – Present

Consultant & Owner

Qualiance ApS, Copenhagen (Denmark) – http://www.qualiance.dk

Providing Life Science companies support with software development to more traditional statistical programming tasks for clinical trial analysis. Qualiance provides expertise in trial programming, project management, standards development and implementation, quality system updates, data de-identification and software development.

Consulting / Biometrics

2014 – Present

Project Lead, PhUSE Data Transparency Working Group

PhUSE Ltd. – http://www.phuse.eu

The PhUSE Data Transparency Working Group defines data de-identification standards for CDISC data models and includes 30+ members from Academia, CROs, Pharmaceuticals, Software and Service organizations. The Working Group released in 2015 the PhUSE data de-identification standard for SDTM 3.2 and is currently working on a similar one for ADaM and has a focus group on interpretations of Policy 0070.

Not-for-Profit Professional Association

2008-2009

Associate Director, Statistical Programming

Ferring Pharmaceuticals A/S, Copenhagen (Denmark) - https://www.ferring.com/

Heading up a group of 8 statistical programmers together with a strong outsourcing strategy involving external partners from Denmark, India and the US. The department directly supported the different Ferring clinical projects with production of SAS ADaM datasets, integrated databases and reporting programs and applications. In charge of updating Ferring's quality system with respect to Statistical Programming.

Pharmaceuticals

2004-2008

Statistician

Novo Nordisk A/S, Bagsværd (Denmark) - http://www.novonordisk.com/

Throughout Novo Nordisk's centric organisation, I worked in parallel on different projects:

May 2007 to October 2008: Standardisation Manager

In charge of coordinating design, implementation, validation and maintenance of SAS standard programs producing standard reports to be used in the reporting of Novo Nordisk's clinical trials across our Danish, American and Japanese R&D centres. The group consisted of SAS programmers, statisticians and medical writers and development was outsourced to India

May 2005 to October 2008: Biostatistician supporting Health Economics analyses
In charge of statistical input for different trials and publications in Health economics across projects within Novo Nordisk's haematology therapeutic area. See appendix.

May 2005 to October 2007: Functional expert on Novo Nordisk Clinical Data Warehouse project
In charge of the statistical computing environment and standard analysis reporting modules functional design under a SDD 3.2 platform and quality system around standard program development.

June 2004 to May 2005: Trial statistician Designing, planning, analyzing and reporting the statistics in clinical trials from phase II to III

Pharmaceuticals

2002-2003

Biometrician

Retinalize A/S, Hørsholm (Denmark), https://retinalyze.com/ (The company was shut down in 2003 and relaunched later on by new owners)

Developing retinal imaging programs, conducting clinical studies with hospitals across markets, validating and maintaining different C++ applications.

Medical Image Analysis

EDUCATION AND TRAINING

1999-2002

MSc. Applied Mathematics & Computer Science

ENSIMAG (Grenoble, France) – http://www.ensimag.fr

- Statistics, Medical Image Analysis, Scientific Computation

ADDITIONAL INFORMATION

Relevant Publications

- *"PhUSE De-Identification Working Group: Providing De-Identification Standards to CDISC Data Models",* Jean-Marc Ferran, Khaled El Emam, Sarah Nolan, Boris Grimm, Nick De Donder. PhUSE Annual Conference 2015

Relevant Presentations

- *" Integrating the new EMA requirements on public disclosure in the study conduct"* - PhUSE Annual Conference 2016, Copenhagen PhUSE SDE 2016
- *"PhUSE Data De-Identification Working Group: Providing De-Identification standards to CDISC data models"* – PhUSE Annual Conference 2015, CDISC European Interchange 2015, Paris, Tokyo and Frankfurt PhUSE SDEs 2015 and Fifth SAS CTDT installment.
- *"Data De-Identification: New Challenges for the Data Scientist"* – Copenhagen PhUSE SDE 2015
- *"Data Transparency: Data De-identification and the Role of the Programmer"* – PhUSE Annual Conference 2014
- *" Data Transparency: Important Considerations for Data De-identification and Sharing Platform"* – Copenhagen and London PhUSE SDEs 2014

Relevant Projects

- Data and Document Anonymization Solution SME for a Software Company
- PhUSE Data Transparency Working Group Project Lead

- Data De-Identification Methodology Definition for Internal Data Sharing for a top-5 pharmaceutical company
- Clinical Trial Disclosure System Implementation
- EudraCT XML Tool Development & EudraCT Reporting for over 50+ studies
- Data Transparency/De-Identification Consulting for a mid-size pharmaceutical company
- Data Transparency/De-Identification Implementation for a top-20 pharmaceutical company acting as Date De-Identification Track Lead

Conferences
- Numerous PhUSE, CDISC and Data Transparency conferences

Memberships
- PhUSE – Board of Directors
- CDISC CTR2 Project Member
- Health Canada Reference Group for Implementation of Public Release of Clinical Information