

BARBACHANO YOLANDA | BSc, PhD

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PROFESSIONAL PROFILE

Ex-regulator and biostatistician, with over 20 years' experience designing, analysing and interpreting the results of clinical trials. An expert in regulatory acceptability, with over a decade working as a regulator in the European system (MHRA and EMA) across all disease areas. Also experienced in preparing submission packages for FDA, particularly in oncology.

I help drug development companies navigate regulatory challenges, by providing the insider statistical perspective necessary for successful regulatory interactions.

CONSULTANCY SERVICES

Semita Regulatory Statistics

- Statistical support developing strategy to provide adequate evidence of efficacy for a MAA
- Support in preparing for regulatory interactions, by reviewing draft briefing books, helping improve the statistical/study design questions where needed, and anticipating questions that the regulators may ask
- Attending the meetings with regulators if needed
- Review of draft protocols or protocol amendments, focusing on regulatory acceptability of the study design, type I error control, estimands and statistical analysis planned
- Mock statistical assessment of final CSR in preparation for submission
- Help interpreting questions from regulatory authorities and support in providing answers

REGULATORY EXPERIENCE

The Medicines and Healthcare products Regulatory Agency (MHRA) Feb 2012 – Sept 2022

I worked at the MHRA when the UK was still within the EU, and hence most of my work was focused on EMA procedures:

- Responsible for the statistical assessment of marketing authorisation applications focusing on the study design, data handling and efficacy conclusions
- Provided assessment of centralised procedures through the EMA and supported the UK rapporteur at CHMP discussions
- Provided scientific advice to pharmaceutical companies through the national UK procedure and through the EMA as part of CHMP scientific advice
- Contributed statistical expertise to various EMA qualification procedures
- Worked within EMA's biostatistics working party to tackle difficult statistical issues, provide guidance to industry and training for assessors

- Defended the UK position at CMDH and CHMP when necessary
- Sole MHRA member of the HMA/EMA joint task force on big data (member of 2 different subgroups: regulatory acceptability and analytics)
- Triggered a GCP inspection after finding inconsistencies in a submission, provided statistical expertise to inspectors during the inspection and helped identify critical findings

Within MHRA, I became a leading senior assessor:

- Responsible for checking the answers given in MHRA scientific advice letters before they were sent out to Industry
- Co-authored guidance for industry on the use of real-world data for regulatory submissions
- Provided assessments of Covid-19 vaccines under extreme time pressures
- Represented the MHRA at conferences such as DIA and Clinical Trials Europe
- Contributed to external collaborations such as SISAQOL-IMI and the Amyloidosis Forum
- Assessed oncology applications via project Orbis in collaboration with the US FDA and other regulatory agencies

INDUSTRY EXPERIENCE

Having worked at both a biotechnology company and a CRO, I understand that sometimes pharmaceutical companies may need some help understanding the expectations of regulatory agencies. Thinking like a regulator is difficult if you have never been one. This is where I am able to help bridge the gap, and support those companies who lack the internal expertise necessary.

BioNTech Jan 2024 – Oct 2026

- PSI (Statisticians in the Pharmaceutical Industry) chair of the Regulatory SIG
- Providing statistical and regulatory input into clinical development plans, study protocols, clinical study reports and regulatory submission documents.
- Participating in meetings with regulators, developing associated documents and the preparation of associated responses.
- Leading a phase 3 study, including all the preparations for submission to FDA
- Keeping up to date on new statistical methodologies and regulatory guidance, and serving as SME in statistics for clinical development.
- Provided training at the PSI course on Regulatory Guidelines for Statisticians

Quanticate Oct 2022 – Dec 2023

- Lead a team of statisticians in both the statistics and statistical consultancy functions.
- Provided regulatory expertise to small companies who lacked in-house experience
- Provided guidance on statistical issues, complex methodology and regulatory acceptability.
- Supported clients' statistical leads to prepare for FDA submission

PRIOR EXPERIENCE

Before becoming a regulator, I worked for 6 years as a study statistician at a cancer centre (Royal Marsden). Being so close to the patients and the clinicians, gave me great insight into how the data is collected at the source, and the impact that new medicines and clinical trials can have on patients.

EDUCATION

PhD Medical Statistics, University of Sussex, UK	2007
BSc (Hons) Mathematics (First class), University of Sussex, UK	2001

PUBLICATIONS

I am an author of multiple publications, some of which can be found here:

<https://www.ncbi.nlm.nih.gov/myncbi/yolanda.barbachano.1/bibliography/public/>

Including the Guidelines for the Content of Statistical Analysis Plans in Clinical Trials
(DOI: 10.1001/jama.2017.18556)