Julien Tanniou

Expert Statistical Methodologist

Education

2011–2016 **PhD degree in Biostatistics**, *University Medical Centre Utrecht/Dutch Medicines Evaluation Board (CBG- MEB)*, Utrecht (The Netherlands).

2009-2011 **Master degree in Biostatistics**, *Université Paris Descartes*, Paris (France).

2006-2009 **Bachelor degree in Mathematics Applied to Social Sciences**, *Université Bretagne Occidentale*, Brest (France).

Professional experiences

2024–present **Expert Statistical Methodologist**, *Saryga*, France, Fully-Remote.

- Provide statistical input and technical support on methods related to clinical trial designs, complex models, quantitative decision-making and biomarker research,
- Perform research work to develop new methodologies, write and / or participate to writing scientific publications,
- Collaborate with academia (supervision of students, cooperation with universities on research projects. . .),
- Provide trainings to statisticians and non-statisticians.

2021–2024 **Manager Biostatistician**, *Quinten Health*, Paris (France), Fully-Remote.

- Provide leadership, guidance, and strategic input as the lead statistician on one or more project team(s), accountable for all statistical aspects of project(s),
- Develop and implement the global R&D strategies that aligns with the vision and goals of the company,
- Work with directors of other groups to assure that biostatistics services meet the organization's research staff's needs,
- Manage a team of Biostatistics staff and provide training, guidance, and mentorship to staff members.
- Effectively communicate statistical concepts and findings to non-statisticians, including senior management and external partners,
- Represent the company at external meetings, conferences, or with regulatory bodies.

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2018–2021 **Principal Biostatistician/Methodologist**, *University Hospital Brest*, Brest (France), Hybrid-Remote.

- Participate in the development of study protocols/designs (Phase I-III): study objectives, efficacy and safety endpoints, statistical analyses, randomisation and blinding, sample size calculations, missing data, estimands,
- Perform regular methodological literature review,
- Write the statistical section of the protocol,
- Review eCRFs (electronic case-report forms),
- Develop statistical analysis plans,
- Perform statistical analyses (with SAS and R softwares),
- Interpret study results from a biostatistical and methodological perspective,
- Prepare clinical study reports,
- Contribute and review abstracts, posters, presentations and manuscripts for publication,
- Member of the hospital methodological group,
- Followed course: SAS Enterprise Guide.

2016–2018 **Senior Biostatistician/Methodologist**, *Seconded National Expert. Biostatistics and Methodology Support Office. Scientific Division. European Medicines Agency (EMA)*, London (United Kingdom), On-site.

- Provided high quality scientific support to (human) products at every point of the lifecycle from a statistical and methodological perspective (centralised procedures, scientific advices / protocol assistances, qualification advices, PRIME procedures, paediatric investigation plans, business pipeline meetings, etc.),
- Attended committees' or groups' meetings, such as CHMP, SAWP, PDCO, SAG Oncology, or other Working Parties,
- Involved in the Biostatistics Working Party (BSWP) organisation, secretariat, coordination and scientific support,
- Coordinated and supported methodological and therapeutic European guidance documents (subgroups, multiplicity, extrapolation, autism spectrum disorder, diabetes, epilepsy, frailty patients, good pharmacogenomics practice),
- Participated in discussions regarding Real-World Data and Real-World Evidence, as well as Individual Patient Data,
- Organised courses for European regulatory clinical assessors: survival analysis, sampling and sample size calculations,
- Participated in the conception of an EMA internal document aiming at defining the elements of a framework for a structured interaction between EMA and CDISC on the generation and maintenance of therapeutic area standards,
- Involved, as a European Commission expert, in the ICH E17 (general principles for planning and design of multi-regional clinical trials) Implementation Working Group,
- Performed a literature review of European Public Assessment Reports (EPARs) with the aim to investigate the role of subgroup analyses in the process of centralised procedures evaluations,
- Presentations of methodological topics at several international conferences: subgroup analyses, estimands, master protocols (basket/umbrella/platform trials), statistical methodology for the comparative assessment of quality attributes in drug development.

2011–2016 **PhD candidate in Biostatistics**, *University Medical Center Utrecht (UMC Utrecht)/Dutch Medicines Evaluation Board (CBG-MEB)*, Utrecht (The Netherlands), On-site,
Thesis title: "To lump or to split? Statistical evidence of subgroup findings in confirmatory clinical trials and the regulatory perspective". Supervisors : prof. dr. K.C.B. Roes, dr. I. van der Tweel, dr. S. Teerenstra, dr. C.C. Gispen-de Wied, dr. A.J. Elferink.

- Contributed to the improvement of methodology through academic and regulatory research on statistical and methodological aspects regarding subgroup analyses, e.g. personalised medicines, in confirmatory clinical trials (literature reviews, modelling and simulations, theoretical calculations...),
- Obtained five statistical and methodological publications as first author,
- Presented results at different conferences,
- Followed courses: clinical epidemiology, computational statistics, survival and event history analysis, handling missing data using multiple imputation, mixed models, group sequential and adaptive designs for clinical trials, bayesian methods, simultaneous inference.

2011–2016 **Statistical and methodological regulatory assessor**, *Dutch Medicines Evaluation Board (CBG-MEB)*, Utrecht (The Netherlands), On-site.

- Performed statistical and methodological assessments of procedures (marketing authorisation applications and scientific advices/protocol assistances),
- Member of the methodological group.

2011 **6-month internship**, *Department of Biostatistics, University of Copenhagen*, Copenhagen (Denmark), On-site.
Projects: "Risk factors for death of drug abusers in Denmark 2009", "Analysis of approved claims, financial compensation and low Apgar scores for deliveries within Danish hospitals 1995-2009", "A model for the distribution of daily number of births in obstetric clinics based on a descriptive retrospective study". Supervisor : prof. dr. N. Keiding.

2010 **2-month internship**, *Université Paris Descartes*, Paris (France), On-site.
Project: "Ovulatory status and menstrual cycle duration in a population- based sample of French women not using hormonal contraception" (OBSEFF study). Supervisor : prof. dr. J.C. Thalabard.

Teaching activities

2025 Saryga: Causal Inference in Clinical Trials (one-day training). Multi-Regional Clinical Trials (half-day training).

2024 Saryga: Missing Data and Multiple Imputation (one-day training).

2017 European Medicines Agency, course for European regulatory clinical assessors: sampling and sample size calculations.

2011–2016 MSc Epidemiology, Utrecht University: Classical Methods in Data Analysis, Modern Methods in Data Analysis, Mixed Models, Generalised Linear Models, Survival Analysis.

Other activities

2024–present Participation to the research community: Member of Regulatory, Historical Data and Quantitative Decision-Making Special Interest Groups (SIGs).

2019–present Methodological expertise: external request from ethics committees.

2014–present Statistical and methodological review of scientific articles charged by various international journals.

Software skills

- Statistical softwares: R, SAS.
- Mathematical softwares: Scilab, Matlab; LaTeX.
- Microsoft Office (Word - Excel - Power Point).

Languages

French	Level C2	*Common European Framework of Reference for Languages*
English	Level C1	*Common European Framework of Reference for Languages*
Dutch	Level A2	*Common European Framework of Reference for Languages*

Oral presentations at international conferences

10/06/2025 *Decision-Making Criteria and Methods for Initiating Late-Stage Clinical Trials: A Multi-Stakeholder Perspective.* Statisticians in the Pharmaceutical Industry (PSI) Conference, London (United Kingdom).

20/03/2019 *Level of evidence of promising subgroup findings.* Workshop European Federation of Statisticians in the Pharmaceutical Industry (EFPSI) 'Recent Developments in Biomarkers and Subgroups in Drug Development', Gothenburg (Sweden).

06/06/2018 *Regulatory Hot Topics* ; panelist : session 'Regulatory Town Hall'. Statisticians in the Pharmaceutical Industry (PSI) Conference, Amsterdam (The Netherlands).

01/08/2017 *European regulatory use and impact of subgroups evaluation in Marketing Autorisation Applications* ; panelist : session 'Interpretation of Subgroup Analysis in Confirmatory Clinical Trials for Regulatory Decision Making'. Central European Network and International Society of Biopharmaceutical Statistics (CEN-ISBS) joint Conference, Vienna (Austria).

26/08/2015 *Estimation of significant subgroup treatment effect in overall non-significant trials: to what extent should we believe in them.* 36^{th} International Society for Clinical Biostatistics (ISCB) Conference, Utrecht (The Netherlands).

27/08/2014 *Subgroup analyses: time to be specific about their goals.* 35^{th} International Society for Clinical Biostatistics (ISCB) Conference, Vienna (Austria).

19/11/2013 *Level of evidence for promising subgroup findings in a negative trial.* 2^{nd} Clinical Trials Methodology Conference, Edinburgh (United Kingdom).

27/08/2013 *Level of evidence for promising subgroup findings in an overall non-significant trial.* 34^{th} International Society for Clinical Biostatistics (ISCB) Conference, Munich (Germany).

Publications

Zebachi, S., **Tanniou, J.**, Bakker, E., de Vries, S. T., Di Bidino, R., Xoxi, E., Glaser, A., Savarese, G., Hillert, J., Mol, P. G. M., Plueschke, K., Amzal, B., Hayek, G. Y., Moreira, J. (2025). Navigating the Real World: A Scoping Review of Structured Frameworks to Effectively Identify, Evaluate, and Select Real-World Data Sources for Fit-for-Purpose Studies. *Clinical pharmacology and therapeutics*, 118(4), 894–905. https://doi.org/10.1002/cpt.3746

Herman, D., **Tanniou, J.**, Leray, E., Pierret, C., Pilard, Q. (2025). Analyzing recurrent events in multiple sclerosis: a review of statistical models with application to the MSOAC database. *Journal of neurology*, 272(5), 371. https://doi.org/10.1007/s00415-025-13100-5

Jiang, C., Beji, C., Zebachi, S., Hayek, G. Y., Cetinyurek-Yavuz, A., Fayyad, M. B. N., Rodwell, L., Roes, K. C. B., Amzal, B., Gerlinger, C., Porcher, R., **Tanniou, J.** (2025). Decision-Making Criteria and Methods for Initiating Late-Stage Clinical Trials in Drug Development From a Multi-Stakeholder Perspective: A Scoping Review. *Clinical pharmacology and therapeutics*, 117(4), 978–988. doi:10.1002/cpt.3566

Cetinyurek Yavuz, A., Fayyad, M. B. N., Jiang, C., Brion Bouvier, F., Beji, C., Zebachi, S., Hayek, G. Y., Amzal, B., Porcher, R., **Tanniou, J.**, Roes, K. C. B., Rodwell, L. (2025). On the Concepts, Methods, and Use of "Probability of Success" for Drug Development Decision-Making: A Scoping Review. *Clinical pharmacology and therapeutics*, 117(4), 967–977. doi:10.1002/cpt.3571

Lepinet, U., **Tanniou, J.**, Courtois Communier, E., Créach, V., Beaumont, M. (2023). Impact of anthropometric data and physical activity level on the closed kinetic chain upper extremity stability test (CKCUEST) score: A cross-sectional study. *Phys Ther Sport,* 64:91-96. doi:10.1016/j.ptsp.2023.09.004

Demirtas, S., Houssais, C., **Tanniou, J.**, Misery, L., Brenaut, E. (2020). Effectiveness of a music intervention on pruritus: an open randomized prospective study. *J Eur Acad Dermatol Venereol,* 34(6):1280-1285. doi:10.1111/jdv.16149

Tanniou, J., Smid, S., van der Tweel, I., Teerenstra, S., and Roes, K. C. B. (2019). Level of evidence for promising subgroup findings : the case of trends and multiple subgroups. *Stat Med,* 38 :2561–2572. doi:10.1002/sim.8133

Rosetta, L., Thalabard, J. C., **Tanniou, J.**, Ducot, B., Maitrot-Mantelet, L., Rousset-Jablonski, C., Bohet, A., Bouyer, J., Chimenes, A., and Slama, R. (2017). Ovulatory status and menstrual cycle duration assessed by self-collection of urine on pH strips in a population-based sample of French women not using hormonal contraception. *Eur J Contracept Reprod Health Care*, 22(6) :450–458. doi:10.1080/13625187.2017.1410881

Tanniou, J., Teerenstra, S., Hassan, S., Elferink, A., van der Tweel, I., Gispen-de Wied, C., and Roes, K. C. B. (2017). European regulatory use and impact of subgroup evaluation in marketing authorisation applications. *Drug Discov Today*, 22(12) :1760–1764. doi:10.1016/j.drudis.2017.09.012

Tanniou, J. (2017). *PhD thesis : To lump or to split ? Statistical evidence of subgroup findings in confirmatory clinical trials and the regulatory perspective.* ISBN : 978-94-6182-802-6.

Tanniou, J., van der Tweel, I., Teerenstra, S., and Roes, K. C. B. (2017). Estimates of subgroup treatment effects in overall nonsignificant trials : To what extent should we believe in them ? *Pharm Stat*, 16(4) :280–295. doi:10.1002/pst.1810

Tanniou, J., Tweel, I. V., Teerenstra, S., and Roes, K. C. B. (2016). Level of evidence for promising subgroup findings in an overall non-significant trial. *Stat Methods Med Res*, 25(5) :2193–2213. doi:10.1177/0962280213519705

Tanniou, J., van der Tweel, I., Teerenstra, S., and Roes, K. C. B. (2016). Subgroup analyses in confirmatory clinical trials : time to be specific about their purposes. *BMC Med Res Methodol*, 16 :20. doi:10.1186/s12874-016-0122-6

Gam, C. M., **Tanniou, J.**, Keiding, N., and Løkkegaard, E. L. (2013). A model for the distribution of daily number of births in obstetric clinics based on a descriptive retrospective study. *BMJ Open*, 3(8) :e002920. doi:10.1136/bmjopen-2013-002920