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SARYGA
STATISTICS & METHODOLOGY

20 years of experience in the pharmaceutical industry
Recognized expert in Bayesian statistics and quantitative decision-making

Professional Experience

Founder and CEO – Saryga (Jan 2022 – Present)

Statistical expertise to support innovation and decision-making in healthcare

- **Methodological support:** Innovative clinical trial designs, decision-making, advanced statistical models, dose-finding, historical data borrowing, benefit-risk assessment, meta-analyses and evidence synthesis, patient and expert elicitation, portfolio risk-value profiles.
- **Independent expert:** Advisory boards and Data Monitoring Committees, statistical support for regulatory applications, risk assessment for due-diligence.
- **Training courses and seminars**

Statistical Methodologist – Servier (Oct 2018 – Dec 2021)

Statistical expert acting as cross-project consultant

- Support **quantitative decision-making** at project and portfolio levels.
- Boost the performance of **pre-clinical and clinical developments**.
- Develop **innovative statistical methodologies**.
- Provide **training** to statistical staff, and establish **partnerships with universities**.
- Share statistical expertise through international working groups and industry consortia.
- Contribute to Servier's external visibility (posters, publications, conferences).

Main research topics:

- Bayesian designs, historical data
- Decision-making frameworks, probabilities of success
- Portfolio decision-making
- Benefit-risk assessment, patient and expert preference elicitation
- Event predictions, surrogacy

PhD in Biostatistics – Polytechnic University of Turin (Oct 2015 – Sept 2018)

Sponsored by Servier

Topic: Quantitative Decision Making in Drug Development

- Quantitative methods for benefit-risk assessment
- Predictions of success, Go/No-Go criteria, extrapolations
- Evidence synthesis, network meta-analyses
- Portfolio projection over time, financial risk-value profiles, delay predictions

Senior Statistician – Novartis Oncology (Oct 2011 – Aug 2015)

Clinical projects in Oncology

- Responsible for the **global development plan** (Europe, US, Asia, pediatric development, and companion diagnostic) of a drug in Acute Myeloid Leukemia (AML).
- **Phase II/III clinical studies**, including a Phase III registration trial co-sponsored with a US cooperative group.
- Statistical lead for US (FDA) and Europe (EMA) **marketing authorization** applications.
- **Independent statistician** for a Data Monitoring Committee of a Phase II clinical study in Head and neck squamous cell carcinoma.
- Management of project teams and outsourcing.

Main research topics:

- Complex Group Sequential Designs (multiple endpoints, multiple populations)
- Estimands, treatment switching
- Multiple testing procedures
- Simulation models for time-to-event data and predictions
- Statistics for non-statisticians internal training program

Statistician – Servier (Nov 2006 – Sept 2011)

Clinical projects in Neuropsychiatry (Major Depressive Disorder, Alzheimer Disease, Schizophrenia)

- Responsible for **Phase I/II/III clinical studies** and investigator-initiated trials.
- Development plans and submission strategies.
- **Regulatory activities:** marketing authorization applications (EMA, China, Taiwan) and HTA applications.
- Pediatric Investigation Plan.

Main research topics:

- Network meta-analyses
- Multiple testing procedures
- Adaptive designs for dose-finding trials
- Quantitative benefit-risk assessment
- Mixed models, missing data

Internship in Biostatistics – Sanofi (Apr 2006 – Sept 2006)

Topic: Sample size calculation and analysis of clinical trials with recurrent event endpoints.

Active member of statistical societies (Since 2006)

- EFSPI (European Federation of Statisticians from the Pharmaceutical Industry)
- PSI (Statisticians of the Pharmaceutical Industry)
- ISCB (International Society For Clinical Biostatistics)
- SFdS (French Statistical Society)
- IBIG (Italian Biostatistics Group)

Education

PhD in Biostatistics – Polytechnic University of Turin (Italy), 2015 – 2018, cum laude (with honors)

Master in Biostatistics – ENSAI (France's Top Graduate School for Statistics and Data Science), with honors, 2004 – 2006

Master 1 in Mathematics – University Paul Sabatier Toulouse III (France), with honors, 2003 – 2004

BSc in Pure Mathematics – University Paul Sabatier Toulouse III (France), 1999 – 2003

BSc in Informatics – University Paul Sabatier Toulouse III (France), with honors, 1999 – 2003

Publications

Statistical Publications

- **Saint-Hilary G**, Cadour S, Robert V, and Gasparini M. A simple way to unify multicriteria decision analysis (MCDA) and stochastic multicriteria acceptability analysis (SMAA) using a Dirichlet distribution in benefit-risk assessment. *Biometrical Journal*. 2017; 59(3): 567-578. doi:10.1002/bimj.201600113.
- **Saint-Hilary G**, Robert V, Gasparini M. Decision making in drug development using a composite definition of success. *Pharmaceutical Statistics*. 2018; 17(5):555-569. doi:10.1002/pst.1870.
- **Saint-Hilary G**, Robert V, Gasparini M, Jaki T, and Mozgunov P. A novel measure of drug benefit-risk assessment based on Scale Loss Score (SLoS). *Statistical Methods in Medical Research*. 2019; 28(9): 2738-2753. doi: 10.1177/0962280218786526.
- **Saint-Hilary G**, Barboux V, Pannaux M, Gasparini M, Robert V, Mastrantonio G. Predictive probability of success using surrogate endpoints. *Statistics in Medicine*. 2019; 38(10): 1753-1774. doi:10.1002/sim.8060.
- Aubel P, Antigny M, Fougeray R, Dubois F, **Saint-Hilary G**. A Bayesian approach for event predictions in clinical trials with time-to-event outcomes. *Statistics in Medicine*. 2021; 1-16. doi.org/10.1002/sim.9186.
- Menzies T, **Saint-Hilary G**, Mozgunov P. A comparison of various aggregation functions in multi-criteria decision analysis for drug benefit-risk assessment. *Statistical Methods in Medical Research*. 2022. doi:10.1177/09622802211072512.
- Di Stefano F, Pannaux M, Correges A, Galtier S, Robert V, **Saint-Hilary G**. A comparison of estimation methods adjusting for selection bias in adaptive enrichment designs with time-to-event endpoints. *Statistics in Medicine*. 2022; 1- 13. doi:10.1002/sim.9327.
- Abellan JJ, Bonnet N, Carlton A, Frewer P, Götte H, Lawo JP, Madsen J, Sailer O, Thömmes G, **Saint-Hilary G**. Points to consider for quantitative decision-making in clinical drug development. *arXiv*. 2022. doi:10.1002/sim.9327.
- Di Stefano F, Rodrigues C, Galtier S, Guilleminot S, Robert V, Gasparini M, **Saint-Hilary G**. Incorporation of healthy volunteers data on receptor occupancy into a phase II proof-of-concept trial using a Bayesian dynamic borrowing design. *Biometrical Journal*. 2023; 65 (8). doi: 10.1002/bimj.202200305.
- Barnett HY, George M, Skanji D, **Saint-Hilary G**, Jaki T, Mozgunov P. A comparison of model-free phase I dose escalation designs for dual-agent combination therapies. *Statistical Methods in Medical Research*. 2024 Feb;33(2):203-226. doi: 10.1177/09622802231220497.
- Best N, Ajimi M, Neuenschwander B, **Saint-Hilary G**, Wandel S. Beyond the classical type I error: Bayesian metrics for Bayesian designs using informative priors. *Statistics in Biopharmaceutical Research*, 1–14. doi: 10.1080/19466315.2024.2342817.
- Fougeray R, Vidot L, Ratta M, Teng Z, Skanji D, **Saint-Hilary G**. Futility interim analysis based on probability of success using surrogate endpoint. *Pharmaceutical Statistics*. 2024 Jul 2. doi: 10.1002/pst.2410.
- Wiklund S-J, Thorn K, Götte H, Hacquoil K, **Saint-Hilary G**, Carlton A. Going beyond probability of success: Opportunities for statisticians to influence quantitative decision-making at the portfolio level. *Pharmaceutical Statistics*. 2024 May-Jun;23(3):429-438. doi: 10.1002/pst.2361.
- Rondano L, **Saint-Hilary G**, Gasparini M, Vezzoli S. Investigating the impact of Data Monitoring Committee's recommendations on the probability of trial success. *Journal of Biopharmaceutical Statistics*. 2024 Dec 8:1-17. doi: 10.1080/10543406.2024.2430308.
- Serra A, Geronimi J, Guilleminot S, Hadjur H, Riviere M-K, **Saint-Hilary G**, Mozgunov P. A novel approach to assess the predictiveness of a continuous biomarker in early phases of drug development. *Statistical Methods in Medical Research*. 2025 Feb 28;44(5):e70026. doi: 10.1002/sim.70026.
- Barnett H, Mozgunov P, Di Stefano F, Skanji D, Guilleminot S, **Saint-Hilary G**, Riviere M-K. Methodological variations on the incorporation of pre-clinical animal data in Phase I oncology trials. Under review.
- Ratta M, **Saint-Hilary G**, Barboux V, Gasparini M, Skanji D, Mozgunov P. Dual-criterion approach incorporating historical information to seek accelerated approval with application in time-to-event group sequential trials. Under review.

- Hadjur H, Geronimi J, Guilleminot S, Serra S, Riviere M-K, **Saint-Hilary G**, Mozgunov P. Evaluating methods for biomarker cutoff detection: a comparative study in small and unbalanced samples. Ongoing.
- Serra A, Guilleminot S, Geronimi J, **Saint-Hilary G**, Mozgunov P. Adaptive biomarker-based design for early phase clinical trials. Ongoing.
- Liu H, Hua Z, Teng Z, Tang S, **Saint-Hilary G**. Methodological aspects and practical application of drug Quantitative Benefit-Risk Assessment, a Case Study. Ongoing.

Clinical Publications

- D'Ascenzo F, Iannaccone M, **Saint-Hilary G**, et al. Impact of design of coronary stents and length of dual antiplatelet therapies on ischemic and bleeding events: a network meta-analysis of 64 randomized controlled trials and 102,735 patients. *European Heart Journal*. 2017; 38(42): 3160-3172. doi:10.1093/eurheartj/ehx437.
- Burrello J, Erhardt EM, **Saint-Hilary G**, et al. Pharmacological treatment of arterial hypertension in children and adolescents: a network meta-analysis. *Hypertension*. 2018; 72(2): 306-313. doi:10.1161/ HYPERTENSIONAHA.118.10862.
- Williams TA, Burrello J, **Saint-Hilary G**, et al. Computed tomography and adrenal venous sampling in the diagnosis and outcomes after adrenalectomy for unilateral primary aldosteronism: a retrospective international cohort study. *Hypertension*. 2018; 72(3): 641-649. doi: 10.1161/ HYPERTENSIONAHA. 118.11382.
- Bertaina M, Ferraro I, Omedè P, Conrotto F, **Saint-Hilary G**, et al. Meta-Analysis Comparing Complete or Culprit Only Revascularization in Patients With Multivessel Disease Presenting With Cardiogenic Shock. *American Journal of Cardiology*. 2018; 122(10): 1661-1669. doi:10.1016/j.amjcard.2018.08.003.
- Iannaccone M, **Saint-Hilary G**, Menardi D, et al. Network meta-analysis of studies comparing closure devices for femoral access after percutaneous coronary intervention. *Journal of Cardiovascular Medicine*. 2018; 19(10): 586-596. doi:10.2459/JCM.0000000000000697.
- Gaudino M, Lorusso R, (. . .),**Saint-Hilary G**, (. . .), et al. Radial Artery Versus Right Internal Thoracic Artery Versus Saphenous Vein as the Second Conduit for Coronary Artery Bypass Surgery: A Network Meta-Analysis of Clinical Outcomes. *Journal of the American Heart Association*. 2019; 8(2): e010839. doi:10.1161/JAHA.118.010839.
- Iannaccone M, Abdirashid M, Annone U, **Saint-Hilary G**, et al. Comparison between functional and intravascular imaging approaches guiding percutaneous coronary intervention: A network meta-analysis of randomized and propensity matching studies. *Catheter Cardiovascular Intervention*. 2020; 95(7): 1259-1266. doi:10.1002/ccd.28410.
- Valle JW, Abou-Alfa GK, (. . .), **Saint-Hilary G**, et al. Quantitative benefit–risk assessment of data from the phase III ClarIDHy study of ivosidenib versus placebo in patients with mIDH1 cholangiocarcinoma. *ESMO Gastrointest Oncol*. 2025;8:100159. doi: 10.1016/j.esmogo.2025.100159.

Conferences and Seminars

- SFdS Biopharmacy and Health group (French Statistical Society). Paris, France, November 2016.
- PSI conference 2017 (Statisticians of the Pharmaceutical Industry). London, UK, May 2017.
- ISCB conference 2017 (International Society for Clinical Biostatistics). Vigo, Spain, July 2017.
- ISBS-CEN conference 2017 (jointly International Society for Biopharmaceutical Statistics and Central European Network). Vienna, Austria, August 2017.
- SMB conference 2017 (Statistical Methods in Biopharmacy). Paris, France, September 2017.
- EFSPI Webinar (European Federation of Statisticians from the Pharmaceutical Industry), March 2018.
- PSI conference 2018. Amsterdam, Netherlands, June 2018.
- EFSPI Statistical Leaders Meeting 2018. Louvain-la-Neuve, Belgium, 2018.
- IBC conference 2018 (International Biometric Conference). Barcelona, Spain, July 2018.

- ISPOR European conference 2018 (International Society for Pharmacoeconomics and Outcomes Research). Barcelona, Spain, November 2018.
- SFdS Biopharmacy and Health conference 2018. Paris, France, November 2018.
- IBIG Bayesian Day 2019 (Italian Biostatistics Group). Turin, Italy, May 2019.
- ISCB conference 2019. Leuven, Belgium, July 2019.
- PSI conference 2019. London, UK, June 2019.
- EFSPI/PSI webinar, December 2019.
- IBIG Forum 2020. Online, October 2020.
- EFSPI/PSI webinar, December 2020.
- PSI conference 2021. Online, June 2021.
- EMA Innovation Task Force, November 2021.
- PSI training session "Historical data in clinical trials", January 2022.
- PSI conference 2022. Gothenburg, Sweden, June 2022.
- PSI conference 2023. London, UK, June 2023.
- IBIG Forum 2023. Milan, Italy, October 2023.
- PSI conference 2024. Amsterdam, Netherlands, June 2024.
- IBIG Forum 2024. Parma, Italy, October 2024.