**Title**: Scientists dreamt of it, OMARS made it

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**Short bio** :

Marion Berger has been working in the pharmaceutical industry for over 25 years, supporting as statistician various areas such as Toxicokinetics, Toxicology, Pharmacokinetics, Pharmacodynamics, Metabolism, Bioanalysis. Together with her team, she has been specializing in statistical support to CMC development of small molecules for the last ten years so as the development of end-user tools for scientists.

José Núñez Ares obtained his PhD under the supervision of prof. Peter Goos at KU Leuven (Belgium) and worked as a postdoctoral researcher at UW Madison (USA) and KU Leuven. In 2023, he co-founded the software company EFFEX, which aims to become a reference in industrial design of experiments. In addition to his research, José has carried out several consultancy projects for companies in different sectors such as energy, chemicals or pharmaceuticals. Putting research results into practice in an interactive and simple way is what motivates him and is his main concern at EFFEX.

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**Short summary of the presentation** :

The talk will present how, using EFFEX software, it was possible to meet the challenge of providing an OMARS design with 24 runs to assess in one shot both formulation and process optimizations, evaluating the impact of 9 parameters (3 for formulation and 6 for process, amongst which 6 were quantitative and 3 qualitative). Using the OMARS design allowed saving a few months of experimentation and a substantial amount of API. The experiment involved measuring more than 20 responses, of which, finally, 12 responses were selected for optimisation. The design analysis strategy will also be shown, using both EFFEX and JMP software. In this very saturated context, the combination of scientists' expertise and statisticians' analysis is crucial to identify meaningful models and to determine the final optimal settings.

This work has been done in collaboration with the statisticians Loïc LEMARIEY (IVIDATA) and Hugo ZUIN (IPPON Innovation).