

DSS Statistics Seminar

May 13, 2022, 17:00

<https://uniroma1.zoom.us/j/86881977368?pwd=SWRFcVFjMDZTa0lXZk05TE1zNm5adz09>

Passcode: 432940

Bayesian Statistics applied
to Early "Oncology Drug
Development"

Roberto Bugarini

Head of Oncology Biostatistics (ECD), Pfizer, San Diego, CA, USA

Ray Li

Director of Biostatistics (ECD), Pfizer, Cambridge, MA, USA

Oncology dose finding studies, in general, aim at determining the maximum tolerated dose (MTD) reflecting the desire to treat patients who have limited options under the assumption that higher drug doses will have better therapeutic activity. We are describing different methods (ie 3+3, mTPI, mTPI-2, and BLRM). This seminar will feature speakers from Pfizer Inc., to share their insights and the recent statistical innovations to address the challenges.

In addition to safety evaluation, Early Sign of Efficacy (ESOE) is a critical step in all early clinical programs to extend the development of a molecule or not. Robust and consistent calculation of the probability of making the right decision is critical. Innovative methodologies are needed to optimize these calculations and ensure all molecules are assessed in the same way across the oncology portfolio.

Case studies will be discussed for dose finding and the utilization of Bayesian statistics in ESOE evaluation.



SAPIENZA
UNIVERSITÀ DI ROMA