

# 2<sup>nd</sup> International Summit on Clinical Pharmacy

December 02-03, 2014 DoubleTree by Hilton Hotel San Francisco Airport, USA

## Between- and within-patient $n$ -level response surface pathway design in dose finding studies

Sagita Dewi and Stig Larsen

Norwegian University of Life Sciences, Norway

**Background:** The study aims were to introduce and assess the performance of clinically based response surface pathway (RSP) design for dose-finding studies, exemplified by one between-patient study, one within-patient study, and simulation studies.

**Methods:** The between-patient study consisted of 15 women suffering from stage IV breast cancer, while the within-patient study consisted of seven female dogs with metastatic mammary cancer. The studies were conducted to determine the maximum tolerated dose (MTD) of a new anticancer agent named BP-C1 using three-level RSP designs. Adjustment of the dose from one design level to the next was based on a  $k$ -adjustment factor estimated to ensure coverage of the entire predefined dose window. Patient sequences with an equal number of patients as design levels were included in the between-patient design, whereas the same patients were included in all the design levels in the within-patient design.

**Results:** Four of the five patient sequences in the between-patient study and all seven dogs in the within-patient study reached the upper limit of the dose windows without any increase in toxicity. The MTD of BP-C1 was thus found to be higher than the predefined cumulative dose window for both patient groups. In all three scenarios, the RSP design estimated MTDs better than the traditional 33 design.

**Conclusion:** The RSP designs do not need an assumed statistical model, and may be useful in estimating MTD, using a minimal sample size. The  $k$ -adjustment factor ensures complete dose window coverage and the design utilizes more information by allowing multinomial outcomes.

### Biography

Sagita Dewi has her education as medical doctor from Udayana University, Bali, Indonesia in 2001. She has been working as MD at Triwidari clinic Denpasar, Primary Health Care (*Puskesmas*) Laulalang and Bali Indera Hospital. In 2009, she started as PhD fellow at Oslo University, Norway with Prof Stig Larsen and finalized her Thesis in Clinical Research Methodology in 2014. She has 10 publications in international medical journals.

[gitaewi@yahoo.com](mailto:gitaewi@yahoo.com)