Basel Biometric Section of the Austro-Swiss Region of the International Biometric Society

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BBS Seminar on Challenges and Evaluation of Biomarkers

Basel, 07 Dec 2009, 16:00 – 17:30

Basel, Auditorium of the Roche Learning Center, Aeschenvorstadt 56, Basel

PROGRAM

16:00 **Welcome** Michael Branson, President BBS

16:00 - 16:45 Eric Holmgren, PhD (Genentech/Roche, US)

Quantifying the usefulness of PD biomarkers in phase 2 screening trials of oncology drugs

Abstract

The increasing cost and duration of Phase 2 trials are leading drug and biotechnology companies to look for ways to speed up this part of the drug development process. One approach is to rely on pharmacodynamic markers to provide a quick assessment of a drug's activity in Phase 2 instead of waiting for progression events to accrue in sufficient numbers. If such a marker can be shown to be a surrogate of survival, then the justification for its use to assess a drug's activity in Phase 2 is clear. However, it is relatively uncommon that a marker meets all the requirements to be considered a surrogate. It is much more common that a marker is simply a correlate of survival. If the marker is also sensitive to drug effects, then between group differences in changes in the marker may also correlate with between group differences in Survival. So the question arises, how strong does the correlation of between group differences in changes in the marker with between group differences in survival have to be for the marker to be useful. In this paper we look to address how strong this correlation must be by answering the following question. Will the use of the PD marker in Phase 2 as a screen for drugs that will pass to Phase 3 improve the efficiency of the drug development process? Holmgren [1] evaluated the impact of Phase 2 screening trials on the efficiency of the drug development process when the endpoint for the Phase 3 trial is examined in Phase 2 (e.g. survival). In this paper we adapt the framework presented in Holmgren for analyzing the efficiency of the drug development process to the setting where a PD biomarker is used to make the Phase 2 screening decision instead of the Phase 3 endpoint. We take a meta analytic approach to quantifying the relationship between the PD biomarker and the clinical endpoint.

References

1. Holmgren EB. Are Phase 2 screening trials in oncology obsolete? Stat Med 2008; 27 (4) 556-567 (DOI 10.1002/sim.2989)

16:45 - 17:30 Martin Schumacher, PhD (Novartis Pharma AG, Basel)

Class prediction with gene expression data

Abstract

The whole process of the building and application of predictive classification models for personalized medicine will be described, including data generation, sample size estimation, data preprocessing, model building, feature selection and validation. Important experimental and methodological issues will be emphasized.

17:30 End of Seminar