Empowering Biomarker Data to Accelerate Personalized Health Care

Xiuting Mi, Roche (China) Holding Ltd., Shanghai, China

ABSTRACT
Biomarker is playing a more and more critical role in accelerating drug development and driving personalized health care (PHC) forward. Therefore, there is a rapidly demanding need to obtain profound knowledge of gene expression data and biomarker technologies. This poster reflects how biomarker brings innovation to medicine evolution, and presents the urgency that regional biomarker stand-alone studies shall be conducted, following the general statistical and exploratory analytics process over lab data including Immunohistochemistry (IHC), In Situ Hybridization (ISH) and other intensive sequencing data source, like Nanostring nCounter assays. It outlines remaining challenges and inspiring works on current work flow, information visualization, and visual analytics. The expected future work is also discussed in the end.

INTRODUCTION
In Pharmaceutical industry, personalized patient care is about having access to traditional and new data sources including comprehensive diagnostic data, sensor data, real-world data, etc., applying traditional and advanced analytics like machine learning to create meaningful insights, and then realizing value from those insights for smarter and more efficient research and development (R&D) and improving patient access and personalized patient care. Biomarker research is a key component of the PHC Strategy, complementing efforts to access high-dimensional genomics data and conducting appropriated analysis using right tools differentiate from those for current well-established clinical trials. This poster, in perspective of R&D, describes the close collaboration between China Oncology Biomarker Data group (OBD China) and Product Development Biometrics (PDB) expertise, from sample collection, lab process to meaningful results, which enables to prioritize molecule development, inform the design of specific trials and identify R&D opportunities for regional diseases.

RAIONAL
A plot shows how biomarker knowledge would impact on drug development.

WORK FLOW
A process work flow show how OBD team and PDB team work together.
- a. Pathological data generation by OBD China
- b. QC of data by PDB Statistical Programmer Analyst (SPA)
- c. Clinical information and sample manifest by PDB Data Manager and OBD operation
- d. Data analysis plan
- e. Produce tables and graphs by PDB SPA
- f. Further exploration needed? If yes, go to d; If no, go to g
- g. Results interpretation and publication

ANALYSIS
Discuss what analysis will be conducted by PDB.
- a. Analysis Population
  Statistical descriptive summary
- b. The distribution and prevalence of the IHC biomarkers
  Statistical descriptive summary
- c. The correlation between the expression of some of the IHC biomarkers
  Box plot
- d. Prognostic association of IHC biomarker expression and clinical outcome
  KM plot
  Forest plot
- e. Immune Profiling using the Nanostring Immune Panel V4
  Heatmap

FURTHER WORK
- a. Create Rmarkdown template to generate standard outputs
- b. Create a R shiny app for OBD team to explore Nanostring data with clinical information