

Cancer Drug Development: Views from Industry and Academia – Introduction to Drug Development

Faculty Presenter

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Scholar Summary

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Dr. Bernardo H.L. Goulart gave an excellent talk about the perspectives of oncologic drug development and the role of academia in cancer drug development. His talk commenced by reviewing the number of drugs approved over the past decade and the source of patients enrolled in clinical trials, then introduced the question of pricing and value of oncology drugs. The approval process of osimertinib was used as an example to challenge the current regulatory requirement for oncology drug approval. Dr. Goulart illustrated a few areas that academia could contribute to oncology drug development, e.g. biomarker identification in clinical trials, facilitation of the practice of precision oncology, and rethinking of the clinically meaningful benefit. Through examining the conflicts between industry and academia in drug development, he encouraged recognition of unmet clinical need for the design of investigator initiated trials. Dr. Goulart provided practical advice on how to set up a successful academic drug development program. It was extremely helpful for us to understand the pros and cons of investigator initiated, industry-sponsored and cooperative group clinical trials. He concluded the talk by discussing special consideration for junior investigators participating in various types of clinical trials, such as authorship negotiation, patient accrual process, time commitment, etc.