

Janssen's platform trial in evaluating novel compounds in Crohn's Disease

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Abstract: The platform study design concept is proposed as a more efficient means of evaluating novel therapies. The platform study design enables multiple drugs to be evaluated in a clinical study in either a simultaneous or sequential manner. With a solid portfolio in Crohn's Disease, Janssen has designed a phase 2 platform trial to test multiple novel compounds.

We will introduce this case study in two parts. Part 1, the background why Crohn's Disease is selected for Janssen's endeavor on a platform trial, basic platform concept, its major benefits, the protocol structure, and our interactions with regulatory agencies and ethics committees. Part 2, some major differences and challenges associated with our platform study in Crohn's Disease, especially those statistics related, will be shared. These differences include the randomization structure, randomization ratio considerations, Data Monitoring Committee (DMC) set-up, homogeneity evaluations across compounds, data usage in interim analyses and data base locks, among other topics. Some of these differences/challenges are general in platform trials, some of them are specific to Crohn's Disease and Janssen's study design.