IDDI Comments on FDA Draft Guidance on Expansion Cohorts

The need to consider randomization whenever feasible in expansion cohorts

The purpose of IDDI comments on FDA Draft guidance is to **emphasize the need to consider randomization whenever feasible** in expansion cohorts, even though randomization has rarely been used until now in this setting. Our view is that the use of a randomized control group should be considered when designing any clinical trial, including an expansion cohort, **in order to produce an unbiased assessment of a drugs efficacy.**

With a scientifically-driven culture, IDDI has always been at the forefront of methodological research (over 800 scientific publications). We believe that the most efficient and cost-effective way to design and conduct clinical trials is to make the best possible use of advanced and innovative statistical methodology. **We have a particular interest in improving and proposing statistical methods that can make your clinical development more efficient and reliable.**

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