EXAMPLES OF NEW CLINICAL TRIAL DESIGNS AND THEIR IMPACT ON LANGUAGE

TRIAL DESIGN	DEFINITION	CHALLENGES	BENEFITS	LANGUAGE
Master/Main Protocols	Designs that enable the investigation of more therapies or diseases under a single protocol containing more sub-studies. These designs include Umbrella, Basket, and Platform trials.	Requires significant infrastructure, planning, and coordination, and have complex trial designs.	Multiple questions can be answered under the same overarching protocol. More studies can be compiled under the same clinical trial application. Enables safe, quick, and competent delivery of new therapies to patients. Reduces patient burden.	Complexity of trial documentation, volumes of information from sub-trials and number of amendments to clinical trial applications drive more and repeat translation needs. Translations should be planned to account for multiple sub-studies and control of translated content.
Adaptive Designs	Designs that permit pre-planned modifications during study execution as data accrue from trial participants. Changes may include trial population, sample size, study drug administration, or dose.	May complicate execution and statistical evaluation due to frequent interim analyses. Safety profiling difficult due to reduced number of participants.	Reduces timeframe, costs, and the number of patients needed. More likely to find any true benefits of the treatment.	Protocol changes trigger new or repeat translation needs during conduct. Translations should be planned for full trial duration to speed up translations with minimum impact on trial continuation.

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