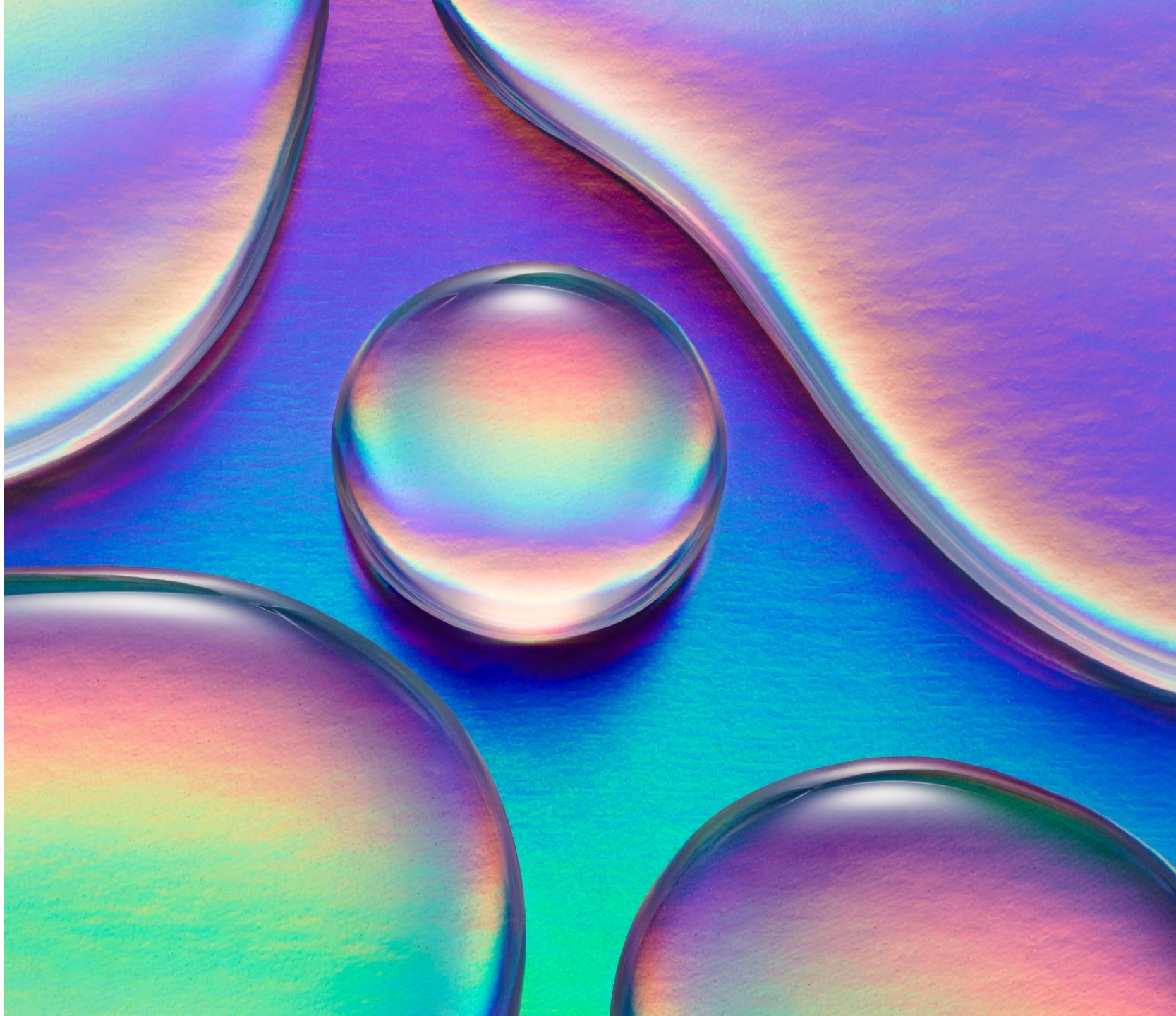


Post Pandemic Trends in Study Designs

Charumathy Sreeraman
Jisha George



Discussion Points

- Master protocol
- Advantages and challenges of master protocol
- Case studies

Master Protocol

A central design divided into sub-studies to evaluate multiple hypotheses, with the goal of improving overall efficiency in clinical trial research

Are being used more frequently across the clinical research enterprise, including in cancer research and in response to the covid-19 pandemic for vaccine research.

“

"A collection of trials or sub-studies that share key design components and operational aspects to achieve better coordination than can be achieved in single trials designed and conducted independently" are employed in the implementation of a master protocol.

”

Advantages

01

Flexibility and efficiency in drug development

02

Reduce trial time and cost from a long-term perspective.

03

Increase benefits of the participants in the clinical trial by adapting to the most rational therapy/treatment based on the participants characteristics.

04

They could collect a lot of high-quality data and engage and educate clinical trial professionals for stable employment since they are long-term, shared trial infrastructure projects with identical standard operating procedures established across sub-studies.

05

Rather than beginning a new clinical trial, master protocols enable adding a new therapeutic discovery after one has commenced and more effectively implementing recent modifications to clinical practices.

06

The rapid growth of precision healthcare mandates the development of increasingly rigorous medicines that require speedy evaluation. The approach of using Master protocol setup shall take precedence considering the existing research attempts to test several treatments or diseases simultaneously.

Challenges

01

These master protocol designed clinical trials are more complex in nature than the traditional clinical trials.

02

The master protocol may also present challenges in study conduct and analysis that, if not properly addressed, may increase risk to humans or delay drug development

03

Master protocol trials require more costs than the budget in traditional clinical trials to establish the needed trial infrastructure and the increased upfront planning and coordination.

04

The intricacy of master protocols has made a few hazards and issues that are neither novel nor essential in conventional trials visible and challenging to manage

05

The abuse of over-complex clinical trial designs might result in unethical conduct of studies and weaken regulatory independence.

06

This approach may lead to constant changes based on interim analysis, this in-turn increases the criticality in planning and budgeting. This also brings up the challenges of amending & approvals in all study documents accordingly time and again.

Types

01



Basket trial - A master protocol designed to test a single investigational drug or drug combination in different populations defined by disease stage, histology, number of prior therapies, genetic or other biomarkers, or demographic characteristics.

02



Umbrella trial - A master protocol designed to evaluate multiple investigational drugs administered as single drugs or as drug combinations in a single disease population.

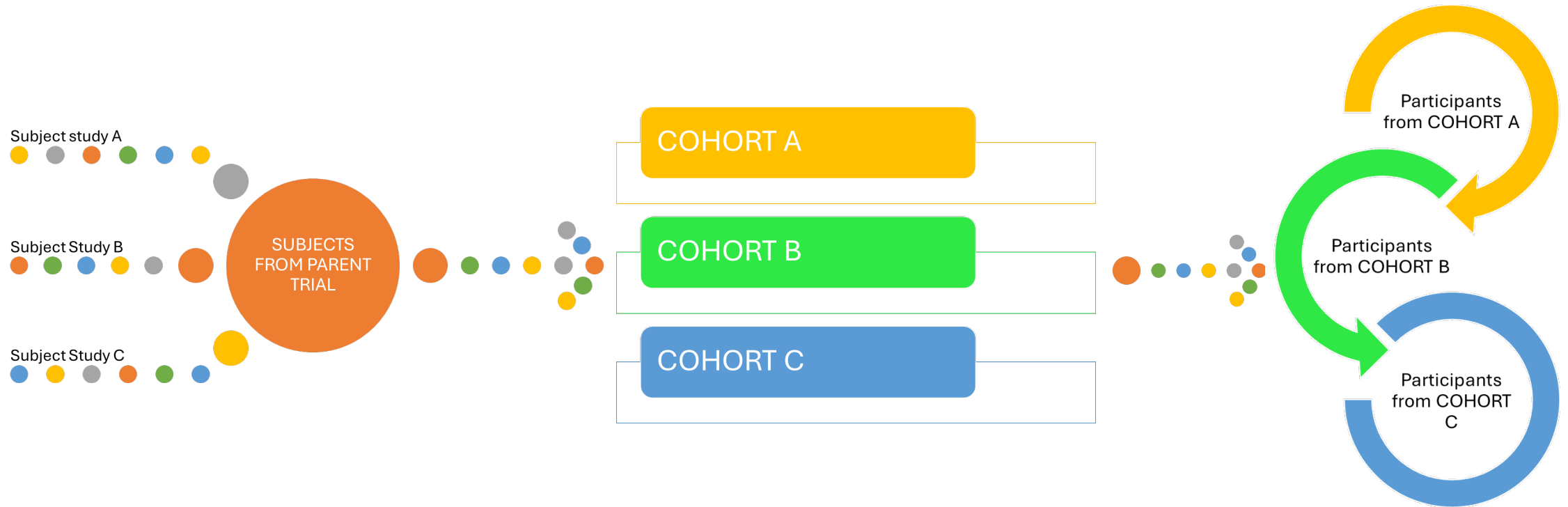
03



Platform trial - A trial designed to study multiple targeted therapies in the context of a single disease in a perpetual manner, with therapies allowed to enter or leave the platform based on a decision algorithm.

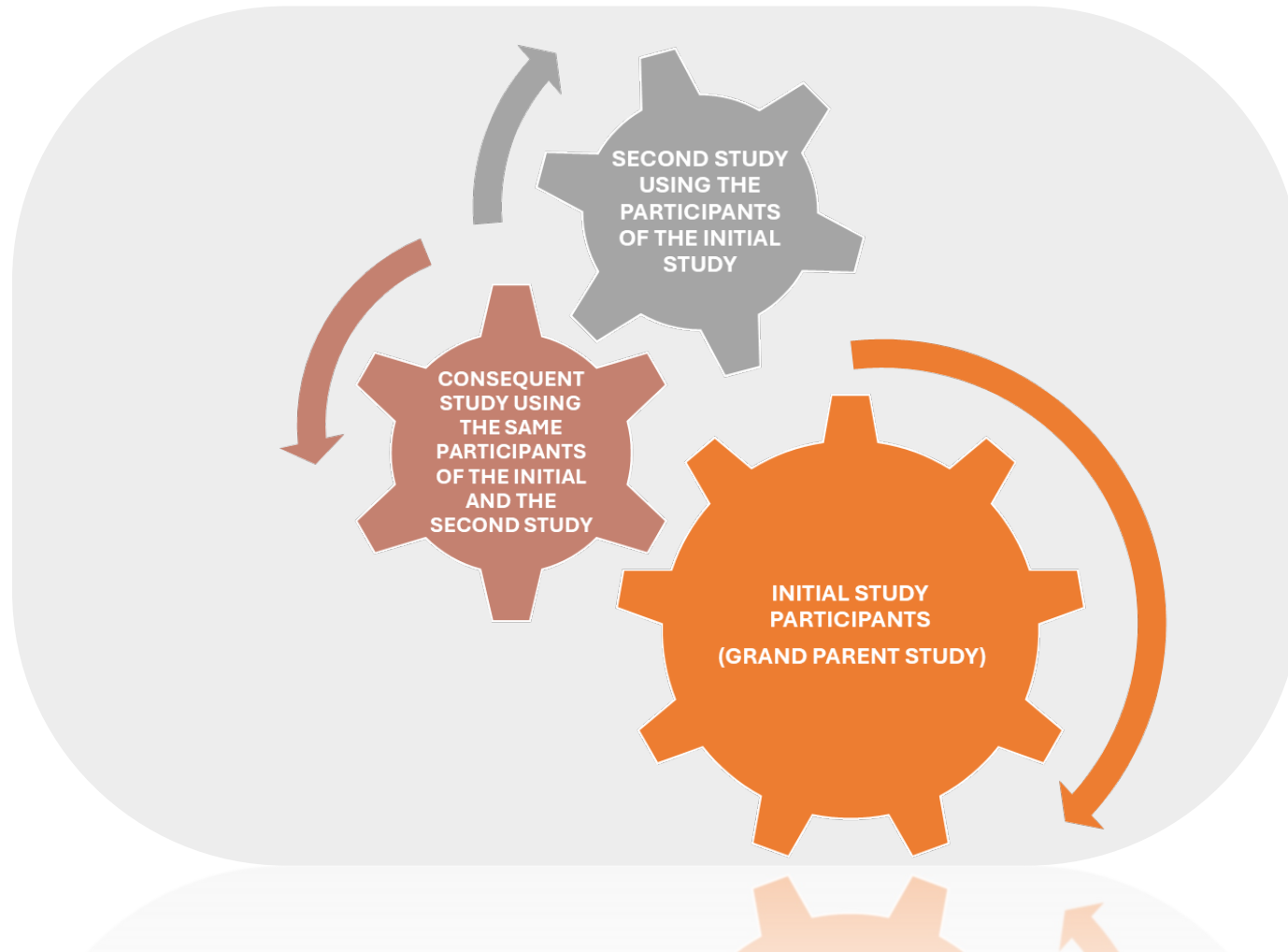
Case Study

Single master protocol with multiple sub studies



Case Study

Parent Study on Initial Strain followed by Child Studies

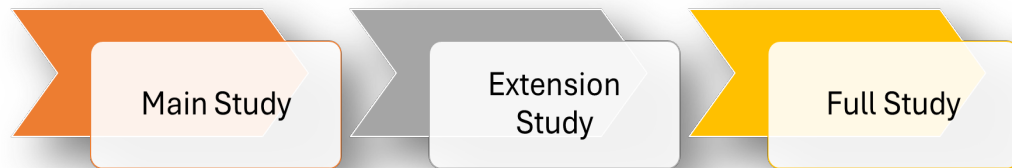


USUBJID Derivation

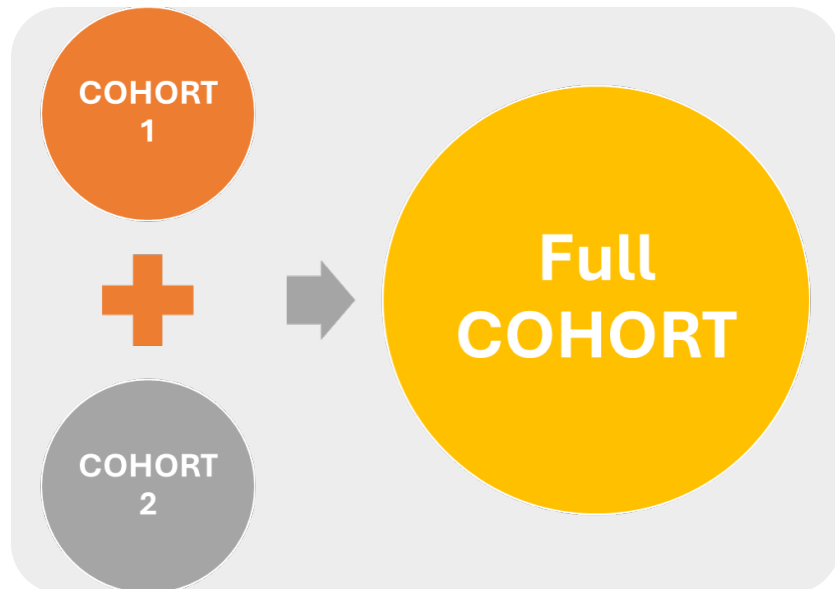
STUDY - I	SUBJID - I	SITE - I	STUDY - II	SUBJID - II	SITE - II	STUDY - III	SUBJID - III	SITE - III	USUBJID
A9999	11561156	1156	B9999	10361009	1036	C9999	10141069	1014	A9999 1156 11561156
			B9999	10361041	1036	C9999	10141070	1014	B9999 1036 10361041
						C9999	10141070	1014	C9999 1014 10141070
A9999	11561156	1156				C9999	10141069	1014	A9999 1156 11561156

Combining Databases of Studies into one

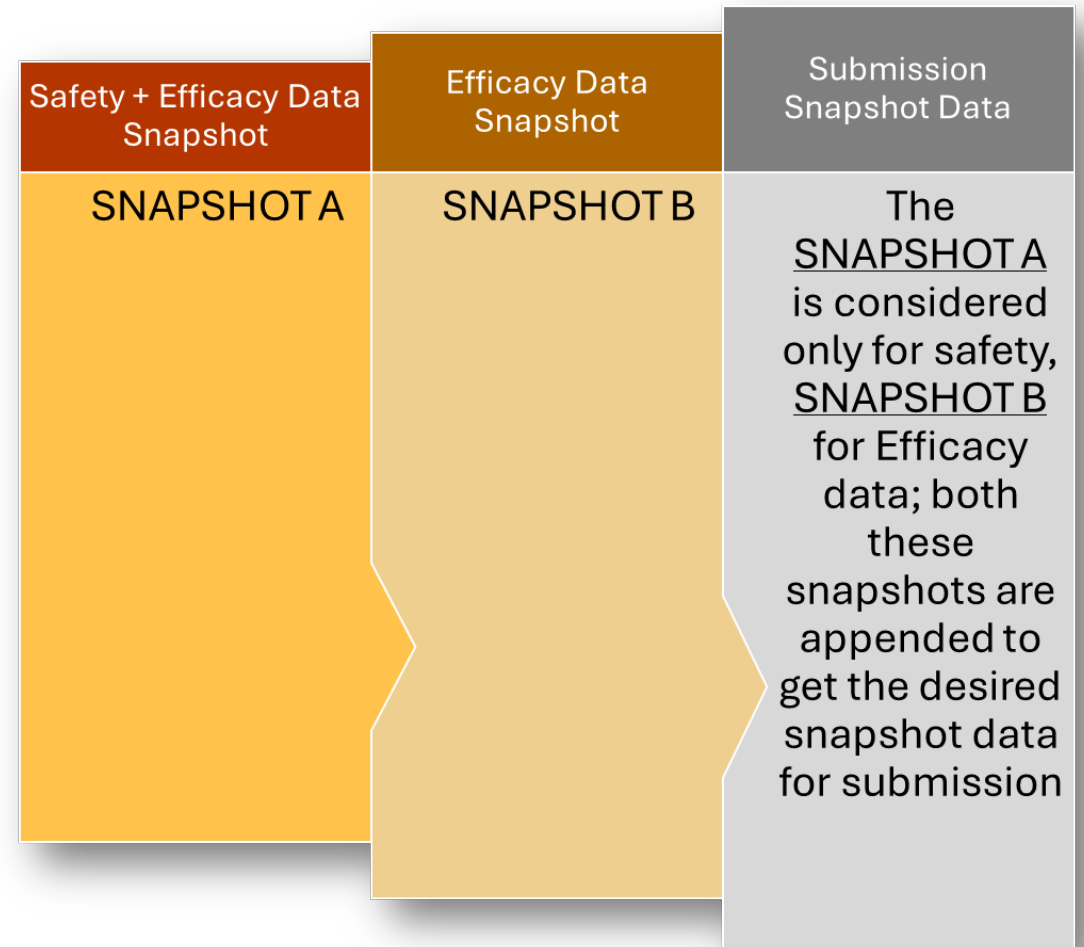
Approach 1



Approach 2



Approach 3



Conclusion

- Master protocols accelerate the drug development trials by testing multiple treatments or multiple sub-populations simultaneously under a single protocol.
- Due to the complexity of the underlying protocols, many problems and risks that are new or not fundamental problems in traditional trials have emerged and are difficult to manage.
- Therefore, master protocols should be used judiciously when they cannot be avoided for scientific reasons.
- The master protocol must be carefully designed and limited to ensure subject safety, data integrity, or research quality.



THANK YOU!