

What is a Master Protocol?

The term “master protocol” generally refers to the use of an overarching protocol that can be used to answer multiple questions. We use it as a broad term, but the actual design of a master protocol can take several forms:

- In basket trials, a single targeted therapy is studied in the context of multiple diseases or disease subtypes.
- In umbrella trials, multiple targeted therapies are studied in the context of a single disease.
- In platform trials, multiple therapies are studied in the context of a single disease in a perpetual manner, with therapies allowed to enter or leave the platform on the basis of a decision algorithm.
- Some master protocol studies will employ a hybrid design approach, employing a combination of innovative design features typically found in basket, umbrella, or platform trials.

It is important to note that both basket and umbrella trials can overlap with platform trials; all are considered master protocol trials. See examples of each type of master protocol below.

