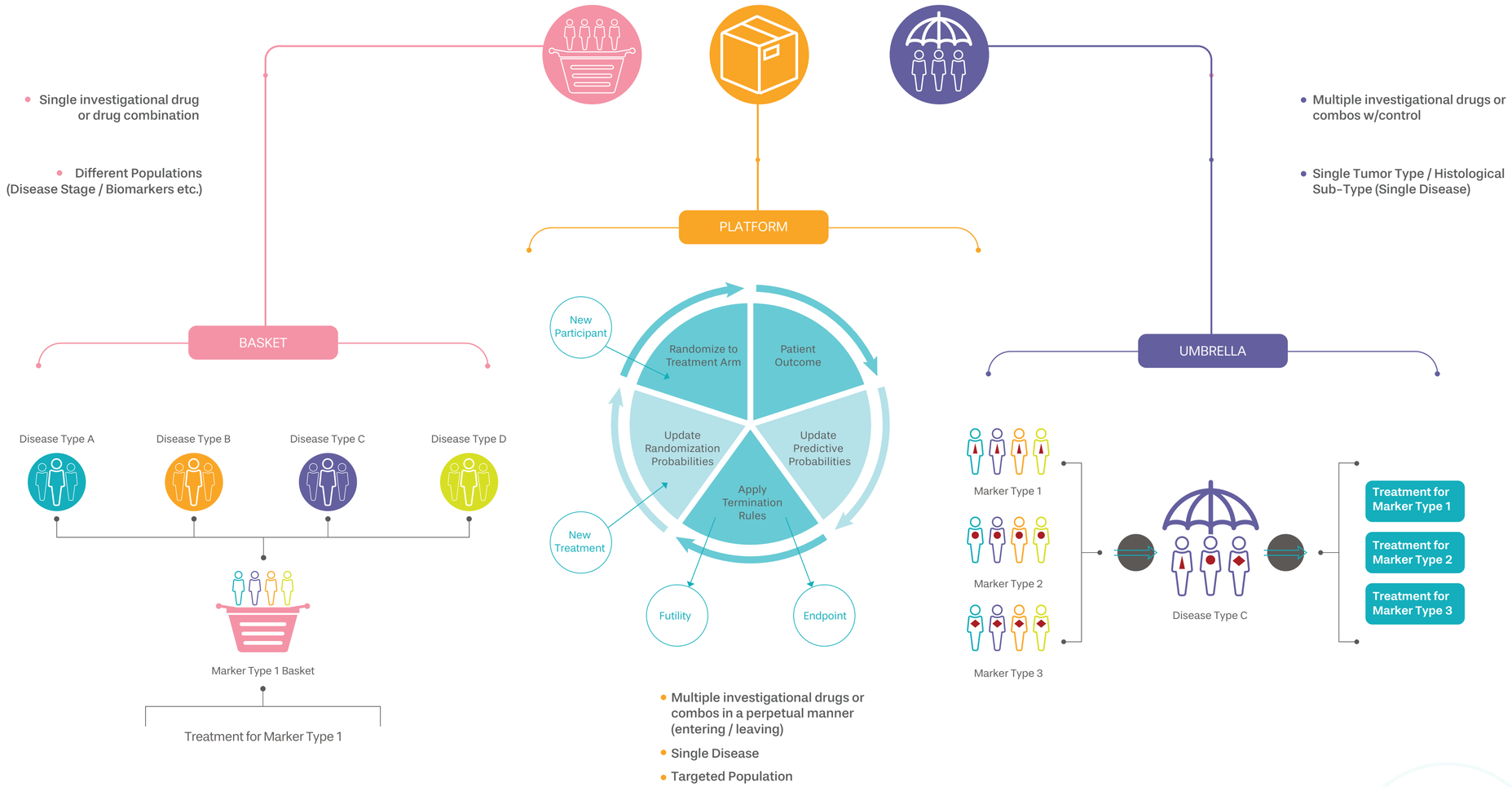
TYPES OF MASTER PROTOCOLS



What should Sponsors be thinking about when planning to run these types of studies?

- Increased up-front planning and coordination for a plan that incorporates all of the most likely scenarios
- Added time and resources to establish the needed trial infrastructure
- Continually adjusting supply strategy
- Centralized, readily extractable data
- Flexible randomization configurations
- Extensive overall flexibility and control

What IRT functionality* is critical to successfully managing these types of studies?

- Flexible visit schedules and dispensation plans
- Ability to add new drugs/kit types to a study post system go-live
  - Drug manager – admin function
  - Add drug to study, set dosing units/increments, set dosing attributes, set kit types for drug and dispensation rules
- Ability to add new treatment arms to a study post system go-live
  - Treatment arm manager – admin function
  - Create treatment arms, set allowable number of cycles and cycle characteristics, set participating sites, adjust cycle visit dispensation rules
- Ability to assign site eligibility for each sub-study
- Management of subject eligibility conflict across multiple sub-studies
- Robust cohort management capabilities
- Advanced randomization scheme incorporation

What do you think poses the biggest challenge to conducting a successful trial with a platform, basket, or umbrella design?

Poll Results (single answer required):

In a recent survey** of 100 respondents, it was indicated that experience and technology are their biggest concerns. That's why you need an experienced technology provider to help deliver these complex trial designs, taking critical IRT functionality* into consideration.

**Survey was conducted during the X-Talks webinar, Top 10 Things to Consider When Designing Platform, Basket, and Umbrella Clinical Trials on May 9, 2019.