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Decentralized Clinical Trials – Umbrella Trials

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Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The views expressed here are of our own and are not related to my employers.*

Aim

- *We are going to discuss on Decentralized Clinical Trails in particularly Umbrella Trails in the post covid era.*



Agenda

1. Why we need Decentralized Clinical Trials?
2. Various examples of Decentralized Clinical Trial Concepts
3. Umbrella Protocol Design
4. Distinction between Basket and Umbrella trials
5. Decentralized trials progression
6. Benefits with Decentralized especially Umbrella trials
7. Q&A

Why we need Decentralized Clinical Trials

It is well evident that safety and efficacy data collected from randomized controlled trials (RCT) provide high quality data on restricted patient populations and has been standard for determining market authorization. There are reasonable benefits in using RWE:

Less time and cost to produce meaningful data

Ability to capture additional information

Social determinants of health that can impact health outcomes

Detection of uncommon adverse events

Better utilization of innovative technologies such as AI, ML and Block Chain

Data articulation to achieve 21st century novel clinical research objectives.

Helpful in the generation of subjects pharmacogenomic information and pharmacokinetic differences between individual subjects.

Some Examples of Decentralized Clinical Trial concepts



Clinical

Demographics, EHR Data
lab Test Results, Diagnosis,
Procedures, Pathology
Images, Microbiology Data,
Provider Notes, Admission /
Discharge and Progress
Report, Performance Status



Medication

Administration (Dose,
Route, NDC / RxNorm
codes), Concomitant
Therapies, Point of Sale
Data, (Prescription &
OTC) Prescription Refill,
Allergies



Claim

Medical Claim,
Prescription Drug Claim,
Other Drug and
Treatment Use Data



Molecular Profiling

Genomic and Generic
Testing Data (SNPs /
Panels) , Multi-Omics Data
(Proteomics,
Transcriptomics,
Metabonomic, Lipidomic) ,
Other Biomarker Status



Family History

Historical Data on Health
Conditions and Allergies
Relating to Patient and
Extended Family, Smoking
Status, Alcohol use



Mobile Health

Fitness Trackers, Wearable
Devices, Other Health Apps
Measuring Activity and Body
function



Environmental

Climate Factors,
Pollutants, infection,
Lifestyle Factors(diet,
stress), Other
Environmental and
Occupational Sources



Patient Reported

Patient Reported
Outcomes, Surveys
Diaries (diets, habits),
Personal Health
Records, Adverse Event
Reporting, Quantity of
Life Measures



Social Media

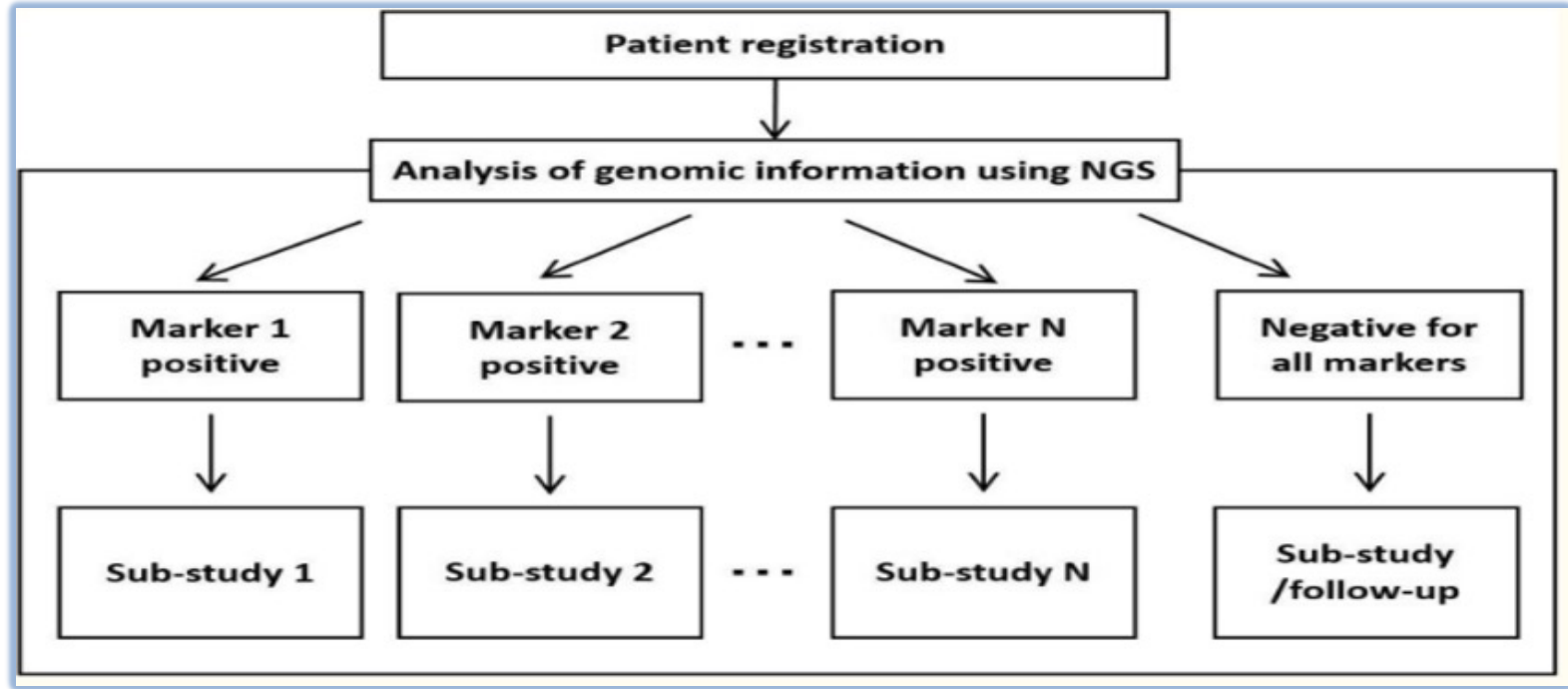
Patient Communication
Twitter, Facebook,
Blogs



Literature

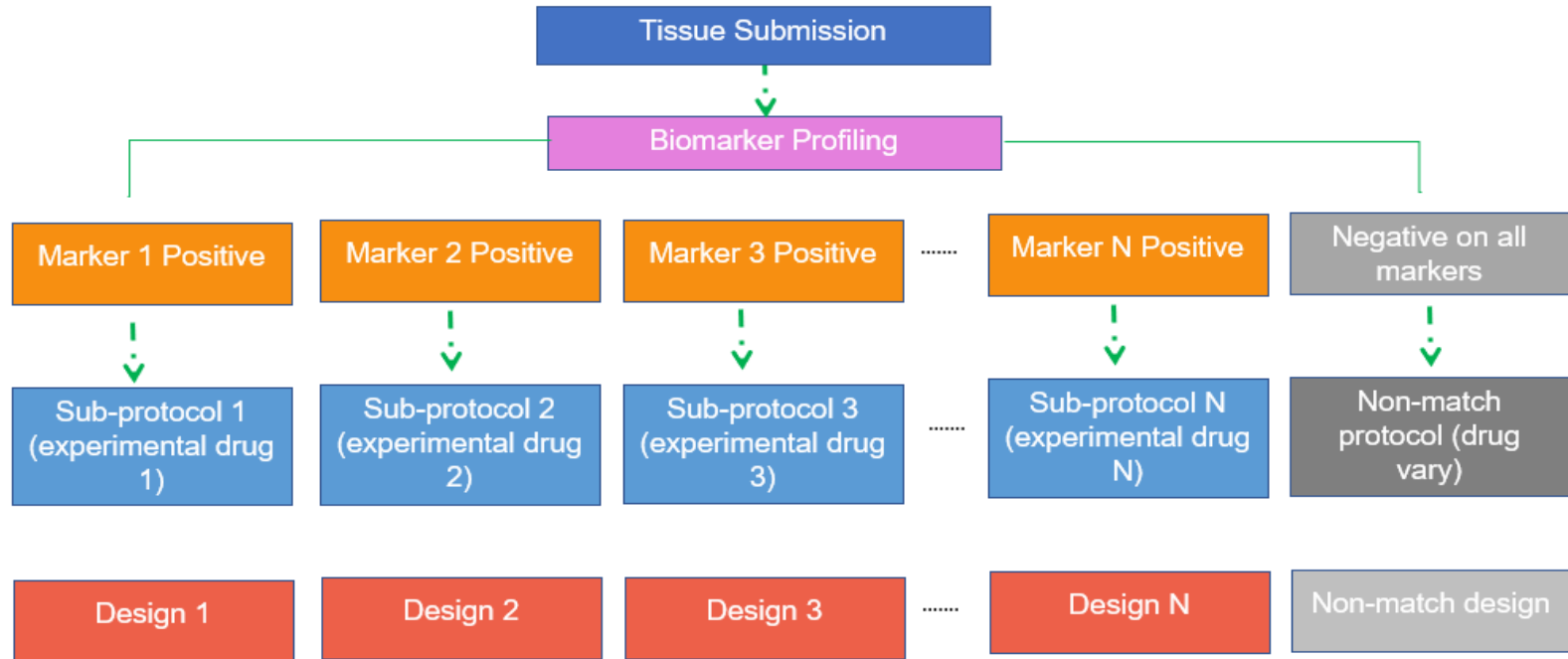
Disease Burden Clinical
Characteristics,
Prevalence/ incidence,
Rates of Treatment,
Resources Use and
Costs, Disease Control,
Quantity of Life Measures

Umbrella Trial Protocol Design



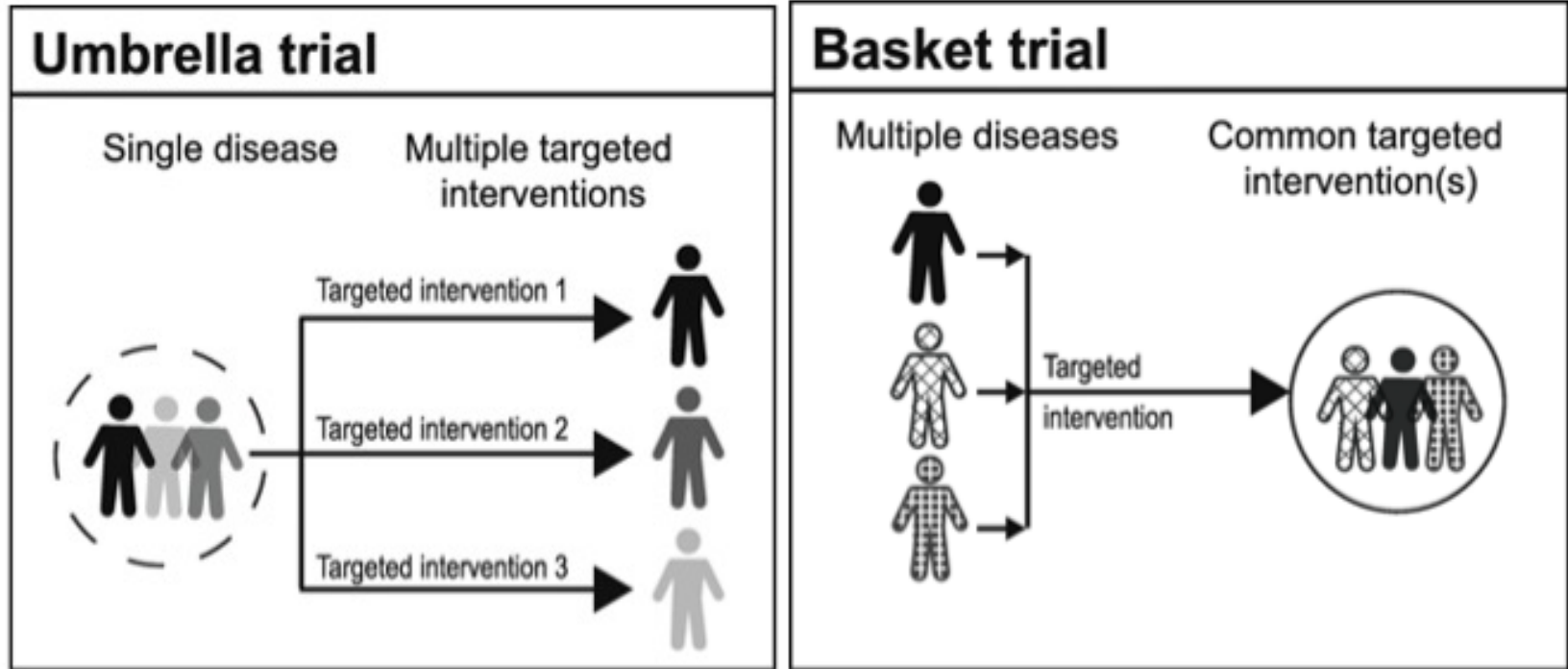
Source: Trails Journal, Article Number:572 (2019)

General Schema of a Umbrella Trial Protocol



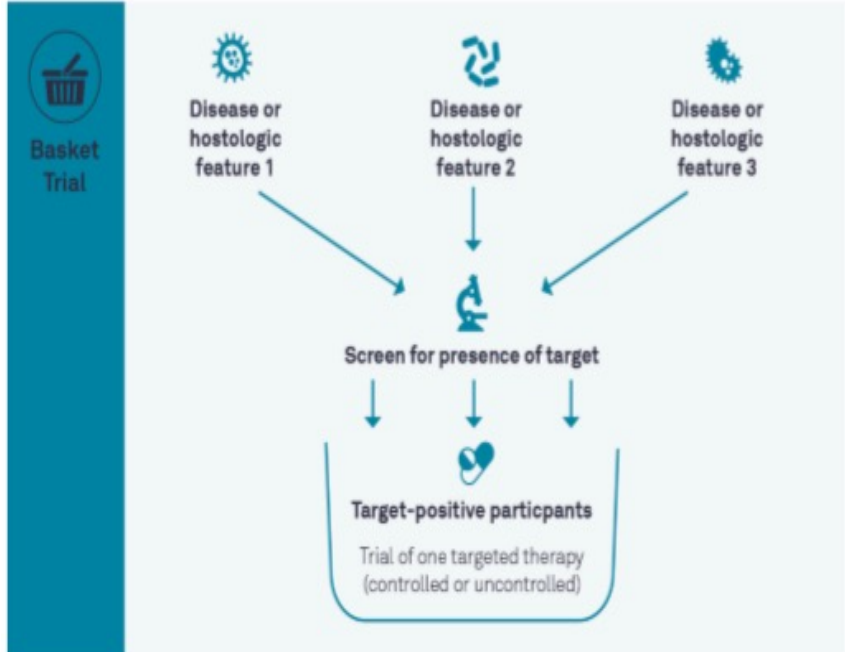
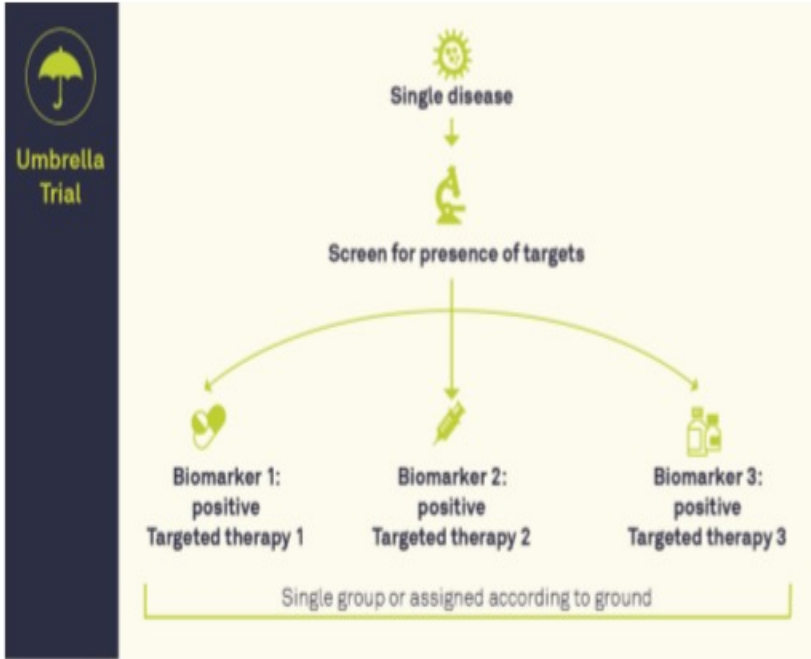
Source: Trails Journal, Article Number:572 (2019)

Differences between Umbrella & Basket Trials



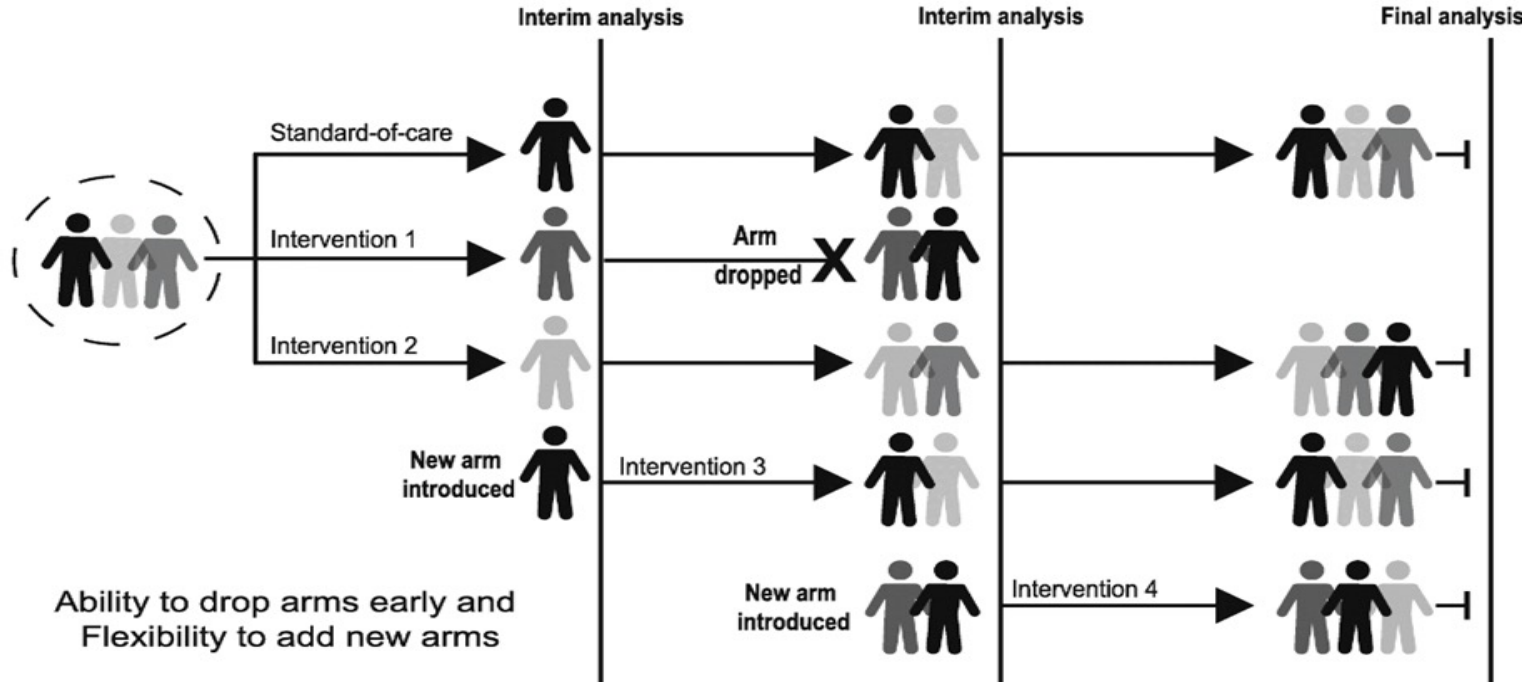
Source: [Jav, J. H. Park et al. Trials, Article Number: 572 \(2019\)](#)

Schematic Diagrams of Umbrella & Basket Trials



Source: [Jav, J, H.Park](#) et al. Trials, Article Number: 572 (2019)

Platform Trial



Source: [Jay, J. H. Park et al. Trials, Article Number: 572 \(2019\)](#)

Estimated Benefits of Decentralized (Umbrella) Trials

Derisking programs

- Quickly test hypothesis, answer scientific questions, and fail fast
- Evaluate and compare treatment combinations or competing drugs

Reducing cost and cycle time

- Faster time to activation
- Partner to share risk and cost

Continuous learning

- Access the latest and best thinking on complex disease area
- Generate real-world evidence

Cost-savings assumptions

Cost component	Estimated reduction in cost (percentage)*
Source data verification costs	10–20%
Site recruitment costs	20–25%
Site monitoring costs	20–25%
Administrative costs	20–25%
Shared cost of control arms	30–35%
Overhead costs	30–35%
Aggregate savings across entire trial	12%–15%

Source: [Jay, J. H. Park et al. Trials, Article Number: 572 \(2019\)](#)

Estimated Savings – Time & Cost with Umbrella Trials

Impact of cycle time savings

Traditional patient enrollment and site-startup time:
117 weeks

Master protocol patient enrollment and site-startup time:
96–102 weeks

Savings: 13%–18%
(15–21 weeks)

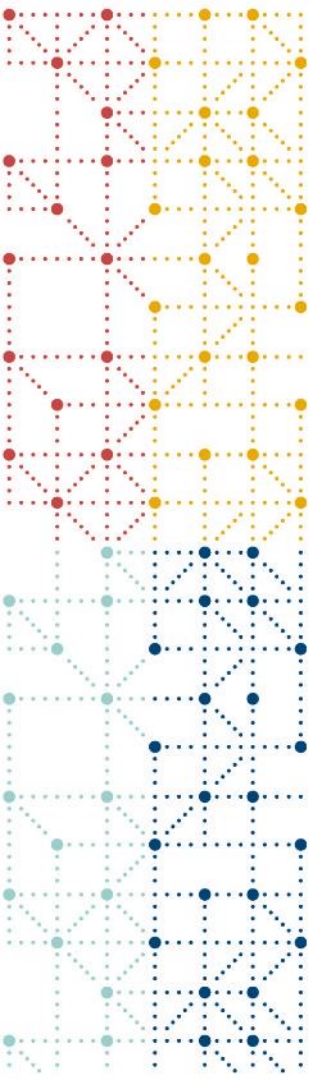
Impact of cost savings

Traditional cost:
\$11.2M

Master protocol cost:
\$9.5–\$9.8M

Savings: \$1.3–\$1.6M
(12–15%)

Source: Trails Journal, Article Number:572 (2019)



Thank You!

Thank you for your
time and attention.

We appreciate the
opportunity to share
Decentralized Clinical
Trials – Umbrella with
you all.