



JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Platform, basket, and umbrella trials

My Dictionary (2nd edition; 2012) has 127 entries with “trial” as a base term. The three terms above are new since publication.

Platform trial

A clinical trial with a single master protocol in which multiple treatments are evaluated simultaneously (fr Saville and Berry; Efficiencies of platform clinical trials: A vision of the future; Clin Trials; 2016 Jun;13(3):358-66. doi: 10.1177/1740774515626362. Epub 2016 Feb 17).

Basket trial

A type of clinical trial that tests how well a new drug or other substance works in patients who have different types of cancer that all have the same mutation or biomarker. In basket trials, patients all receive the same treatment that targets the specific mutation or biomarker found in their cancer. Basket trials may allow new drugs to be tested and approved more quickly than traditional clinical trials. Basket trials may also be useful for studying rare cancers and cancers with rare genetic changes. Also called bucket trial.

(<https://www.cancer.gov/publications/dictionaries/cancer-terms>)

Umbrella trial

A type of clinical trial that tests how well new drugs or other substances work in patients who have the same type of cancer but different gene mutations (changes) or biomarkers. In umbrella trials, patients receive treatment based on the specific mutation or biomarker found in their cancer. The drugs being tested may change during the trial, as new targets and drugs are found. Umbrella trials may allow new drugs to be tested and approved more quickly than traditional clinical trials. (<https://www.cancer.gov/publications/dictionaries/cancer-terms>)

The concepts for basket and umbrella trials are new, but not for platform trials, as noted in a pdf posting dated 12 June 2020.

All three sets of authors extol the virtues of multitreatment designs but as noted in the aforementioned posting, the standard trial has been and remains a two treatment trial primarily because drug companies are not interested in head-to-head comparisons during development.