Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Global Landscape of Novel Clinical Trial Designs: A Cross-Sectional Analysis of WHO-Registered Trials

Hanin Aljohani[1], Ahmed Alkhaldi[1], Alhanouf Alnafisah[1], Sarah Aljahili[1], Shaher Bahkeem[1], Hadeel Alkofide[2]

OBJECTIVES:

The adoption of novel designs in confirmatory clinical trials has shown a rising trend worldwide but the registration data of these designs remains scarce. This study aimed to characterize the frequency, types, and key features of such designs in registered trials.

METHOD:

This study used a cross-sectional analysis of clinical trials registered in the WHO International Clinical Trials Registry Platform up to May 2025. The data cleaning process involved manual inspection of trial records and verification against published protocols whenever possible. The research team first organized trials into design categories (adaptive, umbrella, basket, platform, seamless, pragmatic) before further organizing the studies by phase, number of arms, disease focus (WHO ICD-11), age group and geographic region. Descriptive statistics were used to identify patterns and trends.

FINDINGS:

The analysis included 1430 clinical trials from the total of 1,871 which implemented at least one innovative research design. The majority of studies were Phase II (43.88%), followed by Phase III and Phase I. The majority of trials contained multiple study arms. The research included older adults in 93.3% of trials and pediatric populations appeared in only 6.6% of studies. The therapeutic area of oncology led all other fields with 38.9% of total research followed by infectious diseases. Research conducted at U.S.-based sites made up 44.4% of all studies. The most common design implementation was adaptive (58.2%), followed by basket (14.1%), platform (14.7%), umbrella (10%), seamless (6.9%), and pragmatic designs (1.0%). The majority of umbrella and basket trials focused on oncology research, but adaptive and platform designs were used in both oncology and infectious disease studies.

CONCLUSIONS:

The clinical research landscape experiences changes through novel trial designs although their adaptation varies between therapeutic areas and populations. Broader implementation may be facilitated by stronger methodological frameworks and greater regulatory harmonization.

[1] The Saudi Food and Drug Authority, Riyadh, Saudi Arabia
[2] King Saud University, Riyadh, Saudi Arabia