Transforming Trials: Reducing Cost and Risk

Contributed by

DR. PHIL BIRCH
VP, Strategic Alliance Management
ICON

The total sponsor cost per new drug compound approved in the United States now exceeds $2.5 billion, including nearly $1.5 billion for clinical development — an astounding 145% jump in just 15 years, according to the Tufts Center for the Study of Drug Development[1]. With just 7% of first-in-human drugs gaining FDA approval in the same period, this represents not only great cost but also great risk, in both financial and human terms.

This inefficiency is largely the product of an antiquated drug development system. The traditional manual model of three discrete, fixed trial phases that worked well enough for testing relatively straightforward mass-market drugs is no longer sufficient. It lacks the flexibility, analytic power, and efficiency required to develop complex new therapies targeting smaller genetically distinct patient populations increasingly seen today[2].

ICON is addressing this need through its Transforming Trials initiative. This comprehensive rethinking of the entire clinical trials process uses new approaches coupled with existing, tested technologies to substantially reduce the risk and cost of clinical drug development.

As a continuous quality improvement process, this approach can be successfully applied to any development program, in whole or in part. While its features are evolving, it is based broadly on the following concepts that strengthen clinical trial performance, and serve as a framework for guiding further innovation:

Adaptive clinical trials – Broader use of trials that modify study protocols in predetermined ways based on interim patient data have the potential to eliminate many unanticipated risks that undermine efficacious drugs and unnecessarily extend development timelines.

For example, adaptive approaches often can deliver in a single two-year period combined Phase II/III trial information that otherwise might require three or more consecutive conventional trials over three or more years. These seamless trials reduce the total sample size needed by combining data from patients studied in both phases of the trial. We estimate that optimal use of adaptive trials across a portfolio, which is encouraged by regulatory agencies in Europe and the United States, could reduce trial costs, by 25%.

THE TRADITIONAL MANUAL MODEL OF THREE DISCRETE, FIXED TRIAL PHASES THAT WORKED WELL ENOUGH FOR TESTING RELATIVELY STRAIGHTFORWARD MASS-MARKET DRUGS IS NO LONGER SUFFICIENT. IT LACKS THE FLEXIBILITY, ANALYTIC POWER, AND EFFICIENCY REQUIRED TO DEVELOP COMPLEX NEW THERAPIES TARGETING SMALLER GENETICALLY DISTINCT PATIENT POPULATIONS INCREASINGLY SEEN TODAY.

Automated data collection and analytics – Basing trial inclusion criteria on actual patient data, automatically identified from electronic medical records (EMR), reduces the risk of extra cost and delays when unrealistic recruitment protocols need to be revised. Accessing EMR data can also cut recruitment costs, while automated site support and monitoring greatly reduce start-up and site management costs while ensuring that data are properly collected and validated. Remote data links enable data collection directly from patients at home, reducing the number of costly site visits required for a trial. EMR data allow automated post-market surveillance in Phase IV trials.

Radical patient focus – Improving patients' lives is the ultimate goal of drug development. It means everything from defining outcomes that make the most difference in patient's lives, to offering trials to patients identified through EMRs in their physicians' office, to minimising control arms using advanced statistical methods and providing study results as soon as they are available.

All of these innovations are already in use sporadically, and their individual potential proven. When implemented fully in a systematic way, we believe they could significantly cut clinical trial costs, and reduce time to market by months, if not years.

Expertise in each area, as well as a robust approach to change management, is required to fully implement a more efficient clinical trial process. What will make it all worthwhile will be new drugs brought to market sooner, saving and improving more patient lives. PV

Notes:

[1] DiMasi et al, Tufts Center for the Study of Drug Development, 2014.

[2] Jones DS et al. The Burden of Disease and the Changing Task of Medicine. N Engl J Med 2012;366:2333-2338 June 21 2012, DOI: 10.1056/NEJMp1113569

ICON *plc is a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 87 locations in 38 countries and has approximately 12,500 employees.*

For more information, visit iconplc.com.

ICON

Transforming Trials

We are improving patient recruitment and accelerating the execution of clinical trials through real world EHR datasets

IBM, TriNetX, EHR4CR

100M+ patient lives

Own network of clinical research sites

ICONplc.com