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What Patients? The Trouble With Trial Enrollment

By Ed Silverman // [January 15th, 2013](#) // 10:27 am[29 Comments](#)

There is good news and bad news about enrolling patients in clinical trials. First, the good news – 89 percent of all trials meet their enrollment goals. Now, the bad news – 48 percent of the trial sites miss enrollment targets and study timelines often slip, causing extensions that are nearly double the original duration in order to meet enrollment levels for all therapeutic areas.

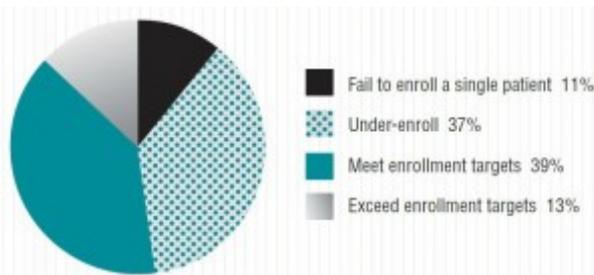
This sobering finding was contained in the latest report from the Tufts Center for the Study of Drug Development, which examined patient recruitment and retention practices in clinical trials. The report suggests that drugmakers and contract research organizations may have difficulty because they rely on traditional approaches. The analysis was based on more than 150 clinical studies involving nearly 16,000 sites in different countries.

Here are some other key findings: 89 percent of all trials meet enrollment goals, but this also means that 11 percent of sites in a given trial typically fail to enroll a single patient. In other words, one out of 10 sites end up without any patients. Meanwhile, 37 percent fail to enroll enough patients, 39 percent meet their enrollment targets and 13 percent exceed their targets. And for a given Phase II or Phase III trial, one of every eight sites exceeds enrollment targets.

The highest site activation rates are in Western Europe, which has a 93 percent rate. A close second is Eastern Europe with 92 percent, followed by the Asia/Pacific region with a 91 percent rate. The lowest rates are in North America, with 87 percent, and Latin America, with 80 percent. “Enrollment achievement rates vary by region, ranging from 75 percent to 98 percent of targeted levels, with Asia/Pacific and Latin America achieving the highest rates,” Tufts writes.

What else? Well, half of all patients screened complete clinical trials overall, though there is wide variation by therapeutic area, according to Tufts. For instance, endocrine studies have the lowest trial completion rates with just 42 percent of all patients screened. And oncology

studies tend to have shorter timeline extensions to reach enrollment levels, compared to endocrine and CNS studies, which have the longest average extensions.



Source: Tufts Center for the Study of Drug Development

And this is interesting: the vast majority of drugmakers and CROs – roughly 90 percent – use traditional recruitment tactics, including physician referrals and mass media, such as newspapers, flyers, radio, and television. Only 14 percent use what are considered non-traditional approaches, such as Facebook banner ads, Twitter, YouTube, electronic medical record reviews, social networking, and online data mining. And this is almost done exclusively in North America, Tufts writes.

Why? The “highly limited use of non-traditional recruitment tactics is a function of real and perceived restrictions by global region, aversion to high-risk approaches, and limited recruitment budgets,” Tufts writes. On a related note, centralized recruitment and retention programs use traditional tactics and tend to avoid nontraditional approaches. And 32 percent of studies do not even receive centralized recruitment support ([here is the Tufts statement](#)).

[**UPDATE:** We are reminded that Pfizer recently undertook an example of 'non-traditional' recruitment tactics. Last June, the drugmaker discontinued enrollment in a study that used social media almost exclusively to recruit patients who would participate from home by using computers and smartphones instead of going to a clinic or doctor's office for medicine and check-ups. Pfizer hoped to create a model for saving money that would rely on personal technology to more easily recruit patients and monitor their progress, but was unable to generate a sufficient number of participants. An updated pilot, though, has been planned ([read more here](#)).]

pie chart courtesy of Tufts CSDD

Comments

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Like Dr House says, 'everybody lies'. Whatever an investigator projects for enrollment I automatically cut in half. Works out just about right.