

Finding the Best Clinical Trial Investigators

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Metrics are great for evaluating clinical trial investigators. They include patient counts from insurance claims, date of last trial, and the number of trials conducted.

How many clinical trial investigators are in the United States, where are they, who are they, and how do you find the best ones? This article presents a newly completed project to answer these questions, and you will see comprehensive statistics that profile investigators. The best investigators enroll patients faster because they have the most patients who match the criteria.

How Many Investigators Are There, and How Did We Find Them?

At the beginning of last year, i3 launched a comprehensive project to identify all investigators from the nation's largest database of private insurance claims, public sources, and proprietary sources. At the end of 2009, 116,165 were identified. Of these, 82,486 are principal investigators and 33,679 are sub-investigators. All are physicians.

The biggest and most important external source was the Bioresearch Monitoring Information Systems (BMIS), which has a public file from the U.S. Food and Drug Administration (FDA). All principal investigators must file a 1572 Form with the FDA every time they do a trial, and BMIS is a log of the filings.

The BMIS file is nearly worthless by itself, because each log entry has little information and is never updated, such as change of address. To resolve this, a computer program created a bridge from BMIS to the nation's largest medical insurance directory, where physicians must maintain current information. The source was Ingenix Provider 360™. BMIS was matched to a database of all practicing physicians, 788,000 in 2009.

BMIS does not release the names of sub-investigators, sometimes called secondary investigators, who assist on the trials. Sub-investigators were found in partnership with Infinata, which culled numerous sources such as trial web postings. The resulting count of 116,165 is verified, current names in 2009, and this is 15% of total practicing physicians. In 2010, first quarter data show 6% more investigators.

What is the Profile of Investigators?

There are several ways to measure and describe investigators: location, experience, hospital affiliation, age and gender, foreign languages spoken, adverse actions, and specialty.

Location. Investigators are concentrated in the more populated areas, as one would expect, but the concentration pattern is not identical to population distribution. The Concentration of U.S. Investigators map, *Figure 1*, shows investigator concentration by state. This is a heat map, with the top states in red or hot colors. The five leading states are Cali-

Figure 1 Concentration of U.S. Investigators

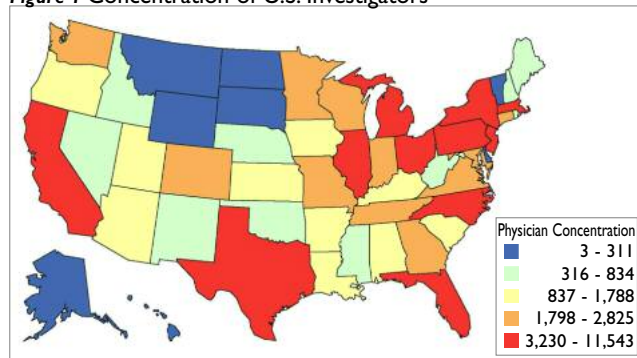


Figure 2

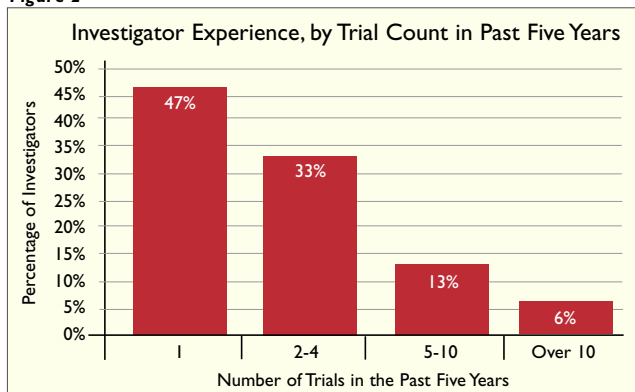


Figure 3

Top 10 Specialties of Clinical Trial Investigators

Rank	Primary Specialty	Count	Percentage of Total (116,165)
1	Internal Medicine	26,933	24%
2	Hematology or Oncology	8,317	7%
3	Family Medicine	7,046	6%
4	Pediatrics	6,219	6%
5	Psychiatry	4,707	4%
6	Cardiology	4,659	4%
7	Endocrinology	4,163	4%
8	Nephrology	3,828	3%
9	Neurology	3,701	3%
10	General Surgery	3,254	3%

fornia (11,543 investigators), New York (8,651), Texas, (7,213), Florida (6,957), and Pennsylvania (5,982). The rest of the states have fewer than 5,000.

Experience. Experience is calculated from the number of 1572 Forms that an investigator has filed with the FDA, one required per trial. The data show light experience, and 47% of the investigators have conducted only one study in the past five years. Those with 10 or more studies are just 6% of the investigators. **Figure 2** shows the full breakout. Thousands of investigators are in the database because they did a trial at one time, but they show zero trials in the past five years. It is important to know when an investigator last worked.

Hospital Affiliation. Hospital access is an important consideration, as many trials are for in-patients or have a hospitalization component. The median investigator is affiliated with a hospital having a bed size of 307. This is very large. Nationally, the American Hospital Association says only 14% of hospitals have more than 300 beds. For clinical trials, the statistic is good news, as the requirements for in-patient clinical trials are usually too heavy for smaller facilities.

Age and Gender. The median age of an investigator is 53, and the middle half of the investigators are between the ages of 46 and 60. This indicates a higher level of medical experience, and one would expect many physicians to get experience before investigating new therapies. The gender split is 79% male and 21% female.

Foreign Languages Spoken. A remarkably high number of investigators have multi-lingual capabilities at their sites, which is good news for racial and ethnic outreach in patient recruitment. Spanish is spoken by 29%. Next in rank are French (7%), Hindi (4%), German (3%), and Italian (3%). Altogether, 42% of investigators work at sites that support at least one non-English language.

Adverse Actions. The FDA takes adverse actions against some investigators for rule violations. In the worst cases, it will bar the investigators from conducting more clinical trials. It reveals adverse actions with public postings on its BMIS web pages. Although anyone who hires investigators should check these listings for problems, they are not much of a factor. Fewer than 100 names are listed.

Specialty. We classified the investigators by their primary specialty, which eliminated duplication. Investigators often have more than one specialty. Internal medicine was the leader by a wide margin, with 24% of the total. The next most common is hematology or oncology (we combined these two), with 7%. Please see **Figure 3** for more details.

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How Do You Find the Best Investigators?

The usual way of finding and evaluating investigators is to take a prior list and fax-blast a questionnaire. While questionnaires are essential, there is universal agreement that most investigators cannot accurately estimate the number of qualifying patients. The inclusion and exclusion criteria are lengthy, and the investigator does not have the time to shift through all the patient charts to find the ones that exactly match.

Fortunately, there is an alternative, which combines a national database of investigators with metrics to rank them all.

The most powerful predictor of success is the patient count by site or investigator. Insurance claims can count specific patients, only those who match all of the inclusion and exclusion criteria. Being specific is especially important in finding investigators with rare patients. The claims information strips off patient identification, but investigator names are visible. When the number of matching patients is high, enrollment will be high too.

My article in the June 2009 PharmaVIEW presented a retrospective study. It showed a statistically significant correlation between the patient count and randomization success. This relationship is also intuitive. The investigators with the most matching patients will naturally have an easier time recruiting.

It's important to watch for data anomalies. For example, there was an incident where 10 investigators claimed to have more than 6,000 attention-deficit patients on their questionnaires. The projection from insurance claims said the real count was 380. This information allowed adjustment and kept the trial out of the infamous rescue mode, which occurs when enrollment falls behind plan.

There are two other metrics that are strong predictors of success. The first is the date of the investigator's last trial, measured from the last filing of the 1572 Form. The investigators who have worked in the past year are more likely to randomize more patients.

The second measure is the number of clinical trials conducted in the past five years. The more trials the better, and the number of patients randomized is highest when the experience is highest.

Finally, everything can be combined into a comprehensive record for each investigator. This is all the profile information presented earlier, plus the evaluation metrics. The industry has the tools at hand to hire better investigators and avoid trial delays. ■

Need a faster approach to trials?

Try metrics.

i3's Clinical Informatics Solutions are the key to better trial planning and less delay.

We leverage the largest database of U.S. private insurance claims to count how many patients match the criteria, site by site nationwide, so you can find the top investigators—who enroll patients twice as fast.

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