

# Locating Patients and Investigators FOR FASTER TRIALS

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here are the patients? Where are the investigators who have access to them? These are early questions in clinical trials, and it is hard to find the answers. Numerous studies show that half of clinical trials run late. Delay starts with the clinical trial protocol, which defines patients using inclusion and exclusion criteria. These criteria are like an attrition funnel for available patients. There are many at the beginning, few at the end.

Tracking shows the problem is getting worse, with sharp growth in the number of criteria. Even if the patients exist, it is hard to find the clinical trial investigators who treat them. Metrics and databases are keys to finding patients and investigators. This article shows four planning steps.

## Step 1: Seeing If Patients Exist

A standard industry practice for finding patients is sending feasibility questionnaires to physicians who work as clinical trial investigators. My company has had a chance to compare the questionnaires to the nation's largest database of private insurance claims, and we proved that investigators lack time to count patients accurately.

There is a better way. An insurance claims database is able to identify how many patients exist, with accuracy, both nationally and at every physician's office. By conducting a clinical trial protocol review, an analyst can translate the words of the inclusion and exclusion criteria into these codes and then count the patients. Additional sophistication is possible, such as using treatments over time to classify patients by stage of disease.

## Step 2: Finding Where Patients Exist

If enough patients exist to fit the predefined target, the next step is finding where they are located. As an example, Figure 1 shows a current concentration map of the U.S. for diabetes, for adults 18 or older, and for all diabetes types, everything in ICD9 diagnosis code 250.

My company's projection is that the national number of diabetics was 18.8 million, 8.1% of the adult population, in 2010. The projection covered patients with all forms of insurance, including Medicare and Medicaid, plus the uninsured. It was limited to patients who presented themselves for treatment. States with the highest percentage concentration are in red. These data would support the decision to target these states when planning site identification. Enrollment is easier where patients exist.

## Step 3: Tightening the Patient Definition

What if you then needed to identify patients with Type 1 diabetes who do not have high blood

### Diabetes Patients Profile

Figure 1

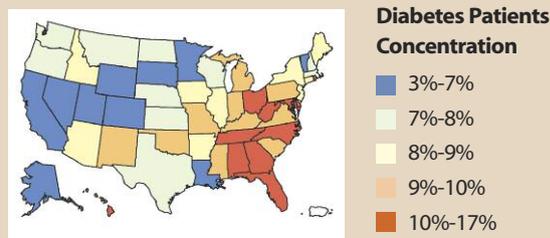
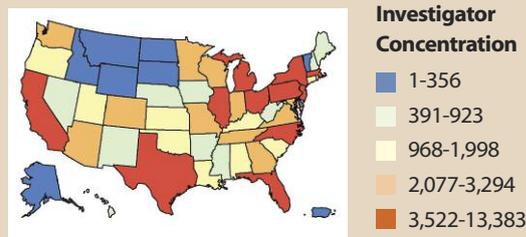


Figure 2



pressure, who do take insulin, and who just had a hip replacement? Flagging these criteria within the dataset would have yielded a much different map. Most protocols have detailed inclusion and exclusion criteria.

This need for detail makes insurance data better than a survey. This article examined 22 million unique lives from insurance claims as the starting point, and then a statistical model created a national projection. In contrast, typical surveys on disease prevalence have fewer than 100,000 respondents. By the time you get to the second or third level of detail, there are not enough people left to answer, so surveys usually stop at whether the respondent has the general disease.

In addition, a person can report having a disease in a survey, but never actually seek treatment from a healthcare provider. Analyzing insurance claims is therefore the best method for determining where the target patients are treated. The 8.1% diabetes prevalence is about one-fourth lower than the reported number in most surveys, but the 8.1% is more accurate. It is important to point out that a patient is not likely to enroll in a clinical trial if not seeking treatment.

## Step 4: Finding Investigators

To find investigators, one powerful technique is to combine insurance claims with an investigator directory. We created the largest national database of U.S. investigators, 122,615 in the first quarter of 2012. The map illustrated in Figure 2 shows the investigator locations.



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The largest investigator name source is available from the FDA. To find secondary investigators not identified by the FDA, we used Web crawlers to discover names on the Internet. This method boosted the U.S. count by a third, and crawlers found about 150,000 investigators in the rest of the world, spread across 170 countries.

Using an insurance claims database, an analyst can create patient count by investigator. For example, a table would reveal that Dr. Smith has 15 patients who match the criteria for a given trial. The analyst would then rank the list by patient count. The list does not identify patient names, but it will reveal the full names and location of the investigators. Many investigators appreciate this shared information, as it facilitates new business from clinical trial sponsors.

We found 31,293 U.S. investigators who treat diabetes, but sponsors do not have easy criteria as defined in this article's example. A typical project would find 1,000 or fewer investigators who have many patients that meet all criteria. The best investigators will have the highest patient count within their own practice, and they will be in the highest disease-prevalence zones.

## Managing Change

Does your company follow these measures when determining protocol feasibility and site identification? If not, data-driven approaches are the wave of the future, and the future is now. **PV**

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