

# Clinical Informatics Solutions

i3's Clinical Informatics Solutions allow you to find new patients, perform clinical trial feasibility assessments, and locate superior study sites. By leveraging the nation's largest private database of insurance claims, i3 is able to count the patients who match the trial protocol and tell you where they are, investigator by investigator, so you can launch trials sooner and complete them earlier.

## A smarter use of claims data— for faster clinical trials

Employ i3's Clinical Informatics Solutions to:

- Obtain an immediate feasibility assessment based on national patient counts
- Redesign protocols by knowing which criteria eliminate too many patients
- Identify the areas of highest patient concentration using county-level maps
- Locate competitive trials
- Rank more than 115,000 investigators by the count of matching patients at each study site
- Recruit patients using an opt-in list of more than 50 million patients
- Recruit patients using insurance claims that identify them back to physicians<sup>1</sup>

## Value to clinical planning

i3's Clinical Informatics Solutions provide the ability to:

- **Create successful protocols**—An analysis of U.S. trials shows a very strong correlation between the number of months of delay and the number of inclusion/exclusion criteria.<sup>2</sup> Evaluate your study by assessing the availability of real patients based on medical conditions, medications, geography, and other metrics.
- **Assess alternatives more quickly**—Assess various protocol criteria at any time to see the effect on patient count.

## Value for finding sites

i3's Clinical Informatics Solutions also enable you to:

- **Optimize investigator selection**—Choose the sites with superior i3 success-predictor metrics to enroll patients more quickly and with greater retention.
- **Create a referral network**—Use i3's "hub and spoke" network report to find physicians with desired patients who are near the trial site.
- **Avoid costly surprises and delays**—Plan resources appropriately from the beginning to meet deadlines and help avoid unwelcome surprises such as needing to add more sites.

## Clinical study delays in the United States

A new tabulation of U.S. trials shows that 45% run late, and 10% take more than twice the time of the original goal.<sup>3</sup> The root causes were underperforming sites, shown below, and growing complexity. In contrast, i3 finds the top performers.

15–20% of sites DON'T perform	Enroll 0 evaluable patients
30% of sites UNDER-perform	Enroll 5% of evaluable patients
20% of sites are AVERAGE performers	Enroll 25% of evaluable patients
30% of sites are TOP performers	Enroll 70% of evaluable patients

## How i3's Clinical Informatics Solutions support the critical stages of clinical trial planning

TRIAL STAGE	DESIGN AND FINALIZE PROTOCOL	SELECT THE BEST SITES		RECRUIT PATIENTS
i3 Services	Feasibility Analysis	Site Ranking	Competitive Assessment	PatientVision Patient Locator
Key Questions	<p>Will the specifications in the protocol allow for enough matching patients?</p> <p>Is there any particular specification that eliminates too many patients?</p> <p>What is the demographic profile of the patients?</p>	<p>Which investigators have specified patients?</p> <p>How do I rank and evaluate potential investigators?</p> <p>Which areas have the highest patient concentrations?</p>	<p>Which areas worldwide have the highest investigator concentrations?</p>	<p>Is there a way to contact patients directly with invitations to the trial?</p> <p>Which potential referral physicians have patients that match the protocol?</p> <p>Can I take insurance claims for identifying matching patients back to the investigators?</p>
Benefits	<p>Identify unrealistic protocol criteria</p> <p>Plan more sites when patient counts are low</p> <p>Identify top back-up sites</p>	<p>Count the patients at each site with greater accuracy than a questionnaire</p> <p>Place sites in the best zones for faster recruitment</p>	<p>Understand competition for investigators</p> <p>Seek popular geographic areas for trials or avoid the over-used ones</p>	<p>Save months of time in enrollment by using the large opt-in database of patients</p> <p>Identify referral physicians and their contact information for faster enrollment</p> <p>Expedite identifying the investigator's own patients who match trial specifications by using insurance claims data</p>
Report Features	<p>Each specification in the inclusion and exclusion criteria works like an on/off switch</p> <p>See the effect of each specification on national patient count</p> <p>"Top 25" reports show leading comorbidities and drugs</p>	<p>Complete contact information and evaluation metrics for each potential investigator</p> <p>Go "inside the walls" of each investigator's practice to count matching patients</p> <p>Map the patient, physician, and investigator pools</p>	<p>Color-coded maps show the number of competitive studies by area</p> <p>Drill-downs go to the ZIP code or equivalent postal zone in other countries</p>	<p>Site lists from i3 will show the number of opt-in patients within driving distance who can be reached by direct contact</p> <p>The "hub and spoke" network report identifies doctors with matching patients who work near the clinical trial sites</p> <p>"Patient Vision" will identify patient names back to the investigator, with appropriate privacy protections</p>
Database Highlights	<p>Continuous claims data on more than 40 million lives</p> <p>Find patients with diagnosis and procedure codes</p> <p>Find patients based on stage and lab values</p>	<p>More than 115,000 total investigators, including over 78,000 principal investigators and 37,000 secondary</p> <p>Data on more than 9 million lives at the investigators</p> <p>Quarterly updates</p>	<p>Integrated comparison of sites</p> <p>Data available by study size and phase, worldwide</p>	<p>The opt-in list has over 50 million names, through i3's collaborative agreement with Acurian, a leading enrollment provider</p> <p>Patient counts are available for more than 750,000 physicians and more than 700,000 allied health professionals</p> <p>Insurance claims can identify patients back to their own physicians</p>

## Sample reports

### FEASIBILITY ANALYSIS BASED ON NATIONAL PATIENT COUNTS

Eligibility Criteria Description	Patients Retained	% Retained
Initial Patients Identified (Right Age and Diagnosis Code)	45,164	100.00%
Exclusion: End Stage Only (Defined with Drug Cocktails)	7,878	17.44%
Exclusion: Peripheral sensory neuropathy	43,065	95.35%
All Inclusions and Exclusions Applied Simultaneously	565	1.25%

*Feasibility Analysis Based on National Patient Counts* shows the patient counts for each of the inclusion and exclusion criteria in the clinical trial protocol. The client for the table above sought end-stage patients for a particular cancer. i3 found 45,164 patients who fit the age and diagnosis code specification. Of these, 17.44% were at end stage, and 1.25% met all specifications for the trial. This was still enough to do the trial because i3 could show the patient count for every potential site. The client hired the sites that had the most of these rare patients.

### Who are the clinical trial investigators?

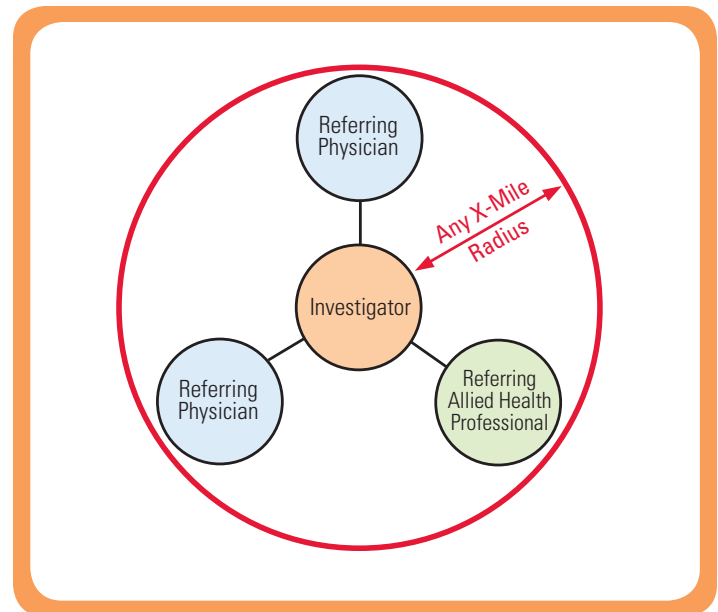
These are the top 25 specialties in i3's investigator database ranked by number of physicians. By drawing on the claims database of one of the nation's largest health insurers, i3 knows where those patients are, investigator by investigator. There are over 80 metrics on each investigator, including contact data that is updated quarterly from insurance claims. Evaluation metrics include the date of the investigator's last trial, the number of trials conducted, and the number of patients who match the protocol. Our studies show that the top investigators enroll patients *twice* as fast.

### TOP 25 SPECIALTIES IN CLINICAL TRIAL INVESTIGATOR DATABASE

Rank	Specialty	Count	Rank	Specialty	Count	Rank	Specialty	Count
1	Internal Medicine	26,933	10	General Surgery	3,254	18	Infectious Disease	2,042
2	Hematology & Oncology	8,317	11	Obstetrics and Gynecology	3,155	19	Orthopedics	1,891
3	Family Medicine	7,046	12	Ophthalmology	3,123	20	Therapeutic Radiology	1,885
4	Pediatrics	6,219	13	Imaging - X-Ray / Nuclear	2,538	21	Emergency Medicine	1,766
5	Psychiatry	4,707	14	Gastroenterology	2,496	22	Dermatology	1,566
6	Cardiology	4,659	15	Anesthesiology	2,401	23	Pulmonary Disease	1,330
7	Endocrinology	4,163	16	Rheumatology	2,323	24	Psychology	1,138
8	Nephrology	3,828	17	Urology	2,048	25	Geriatric Medicine	896
9	Neurology	3,701						

Counts are from the fourth quarter of 2009. Contact i3 for the latest quarterly update.

### "HUB AND SPOKE" NETWORK REPORT FOR REFERRALS

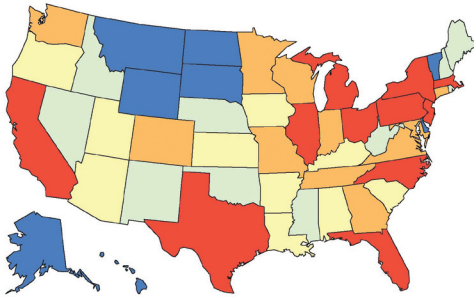


The "Hub and Spoke" Network Report for Referrals identifies potential referring sites ranked by their count of patients who match the protocol. The search looks at nearby physicians and all other health professionals with insurance claims.

## Where are the clinical trial investigators?

Over 120,000 Investigators, Updated Quarterly

### AREA RANKING



#### Investigator Concentration



The i3 database of clinical trial investigators is the largest and most sophisticated of any U.S. database.

## How well does this information work?

i3 recently conducted a retrospective study for a client to assess how well i3's proprietary data predicted investigator success.

### BACKGROUND:

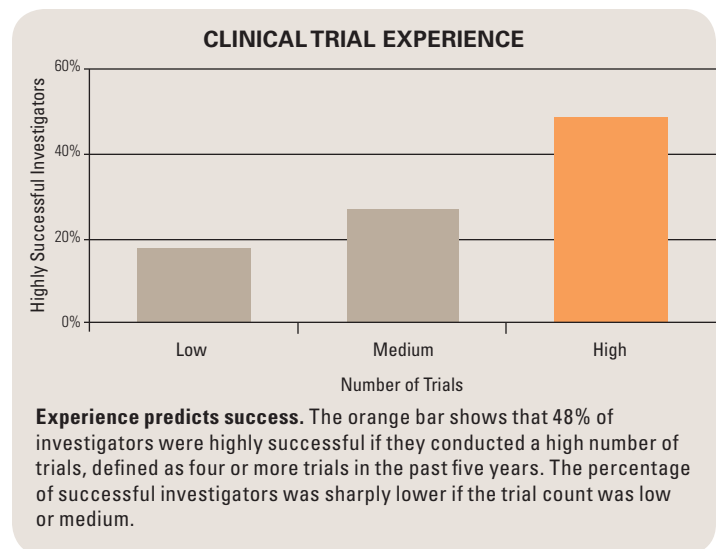
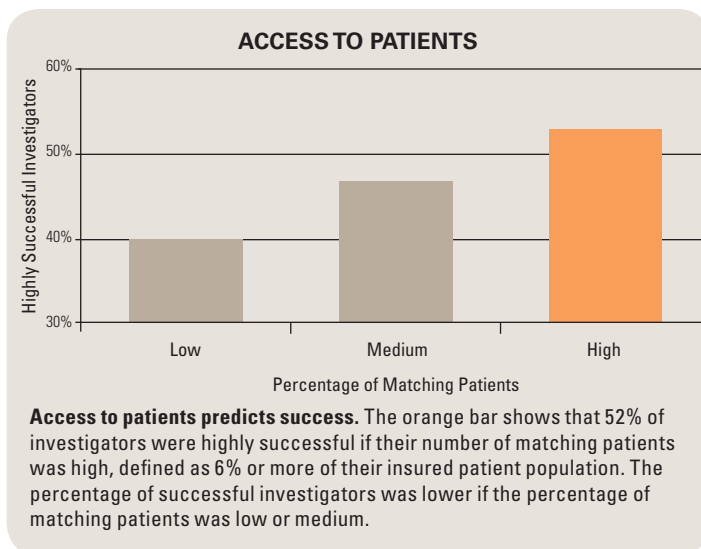
- The study, conducted at 232 investigator sites, was for a leading chronic condition.
- The study looked for highly successful clinical trial investigators who randomized and retained at least four patients. The median in the study was two patients.
- Overall, 37 percent of the investigators were highly successful.

### RESULTS:

The results of our analysis were clear: there were more highly successful investigators when the i3 metrics were high. These i3 metrics forecast success in terms of:

- 1. Access to patients**—The percentage of the investigator's patients who qualified under the inclusion/exclusion criteria.
- 2. Clinical trial experience**—The number of clinical trials conducted by the investigator in the past five years.

The two metrics had even more forecasting power when used together to rank investigators—and the correlation between the metrics and success is statistically significant.



Find out how i3's Clinical Informatics Solutions can assist in your next project.

1. The HIPAA-compliant process protects patient privacy.  
 2. 1,300 U.S. trials analyzed by Clinical Trial Recruitment Strategies, Delphi Pharma's Clinical Trials Database, © Business Insights Limited, 2010. Results are statistically significant.  
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