OPTUM®

Finding the right patients and investigators for faster clinical trials

Are you feeling pressure to complete clinical trials more quickly and cost-effectively than ever before? It's not surprising. Increased competition requires you to find new ways to speed the clinical trial process at every step — without losing quality — so that products can be brought to market faster. So where's the best place to start? With our Clinical Trial Solutions (CTS).

The choice is yours

CTS provides you with two ways to put our expertise, technology and vast health care claims database to work, so you can zero in on the best sites and enroll patients faster:

- CTS custom services — If you prefer a full-service approach, this is it. Our world-renowned analysts will refine protocols, analyze patient and investigator data, create customized reports, and identify sites that are optimal for your trial.
- Optum® Clinformatics® for Clinical Trials — This dynamic web-based software provides you with access to our databases and generates a wide range of valuable reports so you can locate sites and investigators on your own.

In either case, we can help you execute a successful trial with more speed and efficiency.

What we offer:

Feasibility analysis

Full analysis is available with CTS custom services. Summary tables are available with Clinformatics. Using some of the largest available databases of private claims and electronic health records (EHRs) in the United States, this analysis can save you a tremendous amount of time and effort by projecting whether or not your protocol will create enough matching participants. In the full analysis, our experts review each specification to determine how it might affect enrollment. If the projected patient counts are too low, and the criteria are not final, protocol adjustments can be made. If the protocol is final, planning can be done to find more sites and to employ more aggressive patient recruitment tactics, such as direct-to-patient advertising.

Fish where the fish are

By helping you find the largest number of patients who meet your clinical trial criteria, CTS makes it easier to complete your trial on time and within budget.

- Identify the geographic areas with the highest concentration of patients who satisfy your protocol.
- Rank investigators based on patient count.
- Improve clinical trial planning.
- Design more successful protocols.
- Avoid expensive delays.

Data you can trust

We use data drawn from the nation's largest health care claims database.

- More than 170 million unique lives with insurance claims and more than 80 million with electronic health records (EHR)
- Compliant with HIPAA and other privacy regulations
- Extremely accurate — The system cannot count a patient twice.

With the full analysis, the findings are presented either in a "static" Excel table (see example below) or a "dynamic" Excel pivot table. The dynamic table has an on/off switch for each specification, which allows you to experiment with an unlimited number of possible specification combinations and to see instant answers. Similarly, Clinformatics allows you to easily adjust trial criteria to analyze various "what if" scenarios, although its capabilities are more basic.

Static feasibility analysis table

CARDIOVASCULAR PATIENTS SPECIFICATION (EXAMPLE)	NUMBER LOST (%)	NUMBER RETAINED (%)
Patients with unstable Angina or NSTEMI diagnosis (411.1, 410.7)		70,814 (100%)
One of the following risk factors:		
Prior MI within 5 years	55,258 (78.0%)	15,556 (22.0%)
CHF within 5 years	51,619 (72.9%)	19,195 (27.1%)
Age >=60	29,468 (41.6%)	41,346 (58.4%)
Patients Meeting All Inclusion/Exclusion Criteria:	**65,633 (92.7%)**	**5,181 (7.3%)**

You can define a patient using any combination of:

- Age
- Gender
- ICD diagnosis codes
- Current Procedural Terminology (CPT®) codes
- National drug codes
- Events over time
- Disease stage

U.S. site selection

With CTS custom services, investigator lists using highly detailed criteria are provided. Clinformatics generates investigator lists using top criteria only.

Research indicates that an investigator's patient count and experience have a strong positive correlation with the number of patients they are able to randomize and retain. There can be a two-fold increase in trial speed when selecting sites that are ranked highest in these areas, creating a large savings in operating costs and improving your ability to meet deadlines. Meanwhile, related data shows that investigators who have worked on a trial in the past year are significantly more likely to have randomization success. We can help you take advantage of these phenomena with reports that rank investigators according to:

- Date of last trial
- Trial count in the past five years
- Number of patients

Investigator reports are generated using a database of over 125,000 investigators nationwide. Reports can provide you with detailed contact and profile information, such as the investigator's name, address, phone number, fax number and specialty, so you can easily reach out to investigators who will help your trial succeed.

Example investigator report

Physician name	E-mail address	Address	State	ZIP	Specialty	Studies in past 5 years	Most recent study	Number of patients who match inclusion/exclusion criteria (Any combination of diagnosis, procedure, device, and drug)					
								Total (ranked on this)	Hispanic	White non-Hispanic	Black non-Hispanic	Asian non-Hispanic	Other non-Hispanic
Investigator 1	drsmith@aol.com	Kaler St.	TN	37881	Orthopedic	10	1/3/2016	30	8	12	5	4	1
Investigator 2	wwcarl@gmail.com	Oak St.	NC	38117	Internal Medicine	7	8/4/2015	22	3	13	2	2	2
Investigator 3	wyuan@oncology.com	Avon Rd.	NY	10022	Oncology	12	2/22/2016	19	3	11	2	2	1

Clinical Trial Solutions services chart

	Feasibility analysis based on U.S. patient counts	U.S. site selection	International site selection	Hub and Spoke Report for U.S. referrals	Physician list	U.S. area ranking report
CTS custom services	Full analysis available	Full investigator lists created with highly detailed criteria	Available	Optional. Includes U.S. physicians and allied health professionals	Available for U.S. physicians and allied health professionals	Available with detailed customization
CTS online services: Clinformatics for Clinical Trials	Summary tables only	Full investigator lists created with top criteria only	Not available	Available for up to 20 investigators	Available for U.S. physicians	Available

Hub and Spoke Report for U.S. referrals

Report is available with CTS custom services. Report is limited (up to 20 investigators) for Clinformatics for Clinical Trials.

Once the sites and investigators for your trial have been identified, you may want to locate nearby physicians with matching patients who can refer those patients into the trial. Our Hub and Spoke Report can do that quickly and easily.

The report considers an investigator a "hub" and referring physicians the "spokes." Once the hub is identified and the preferred distance from the hub to potential referring physicians is chosen, a report can be generated that ranks those physicians by either:

- Patient count
- Mileage from the hub

The Hub and Spoke Report contains valuable contact and profile information, including the physician's name, ID number, Drug Enforcement Identification number, speciality, phone number and address. In addition to physicians, allied health professionals such as psychologists and physical therapists can be included.

U.S. physician list

With CTS custom services, lists including both physicians and allied health professionals can be created. The Clinformatics online list uses only the names of physicians.

You can use a physician list to create a referral network. The same database of one million physicians used to generate the Hub and Spoke Report is used to produce this list. This list will enable you to:

- Identify which physicians treat the designated patients
- Identify the physicians with the highest patient counts
- See the distribution of patients by physician specialty

As with the investigator lists and the Hub and Spoke Report, this report provides you with extensive contact and profile information.

Optum Medical Provider Database	
Category	**2016 count**
Number of clinical trial investigators	125,000
All medical professionals including investigators:	
Physicians with degree (MD or OD)	527,000
Allied health professionals (Non-MDs, such as psychologists)	1,162,000
Total	**1,689,000**

Breadth and quality — Optum covers virtually all medical professionals, not just those in any particular network. All contact information begins with insurance claims data and is then 100% verified, through millions of calls that reach most offices twice annually. Calls are supplemented by cross-validation of files from CMS, the Centers for Medicare and Medicaid Services.

U.S. area ranking report

Available with both CTS custom services and Clinformatics. Detailed customization available with CTS custom services.

This state-of-the-art tool can help you target the best area for your trial by showing the disease prevalence by patient, age and gender, down to the census region, state, county or Designated Market Area (DMA®)[1] level.

You can view the information on a color-coded national "heat map" (see example to right) or on a table. The map graphically depicts the relative prevalence rates across the country, with the hottest areas — those with the highest rates — in red. The table also provides prevalence rates, along with:

- Projected counts of patients with the selected condition
- Annually updated populations
- Actual number of patients in the database with the condition

An age/gender version of this report is an excellent tool for media planning. The demographic profile includes race/ethnicity data to assist minority targeting.

International site selection

Available only with CTS custom services.

If you need to find investigators outside of the the United States, we have the solution. In partnership with another company, we have identified approximately 200,000 clinical trial investigators in over 200 countries.

A sophisticated set of web crawlers and computer programs were used to gather investigator data wherever posted. This includes U.S. government sites such as clinicaltrials.gov, which often contains site-specific information for foreign sites, other U.S. sites, sites of foreign governments and numerous private sites. Once the data is captured, computer programs assemble and standardize the information.

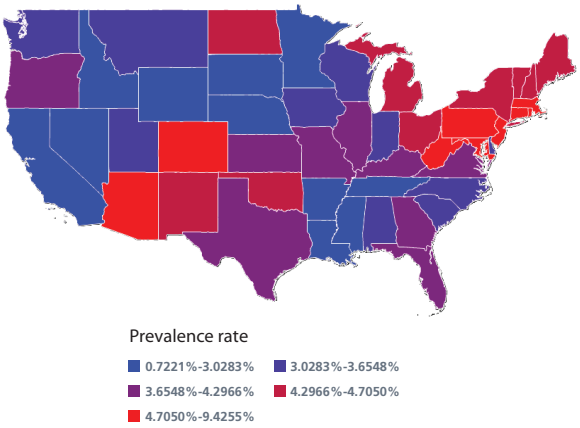
We can use this data to evaluate investigators according to a relevancy score tabulated on a number of variables, such as:

- Trials and articles they have worked on in a therapeutic class
- All indications they have worked on
- A study count of the selected indication

Contact and profile information, such as name, email, phone, location and professional designation, is provided where available. This information may vary by record, but email addresses are typically available. We will share sample lists for evaluation.

Example:

Heat map of the area ranking report for female asthma patients in the age category 18-24



1. DMA® is a registered trademark of The Nielsen Company (US), LLC. A DMA is a greater metropolitan area and represents the definition most commonly used in the planning of mass media purchases, especially TV and radio. There are currently 210 DMAs in the U.S. Optum licenses DMA and population data from Nielsen to ensure an exact match of Optum information with Nielsen's media planning tools.

To learn how our Clinical Trial Solutions can help you save time and resources by helping you choose sites more effectively and enroll patients faster, please contact us.

Call: 1-800-765-6713
Email: connected@optum.com
Visit: optum.com/life-sciences-solutions

OPTUM® optum.com

11000 Optum Circle, Eden Prairie, MN 55344