

Better and Faster Clinical Trials:
**Technology to Target and Communicate with Patients in
Physician Offices**
White Paper

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Abstract: Clinical Trials Enrollment Problems and How ICLOPS Solves Them

Getting drugs to market in the United States requires an enormous amount of money, time, and resources. While there is universal agreement that the high cost of prescription drugs is mainly due to the cost of research, there is little activity toward reducing research costs. Recent accounts of clinical trial shortfalls, and disclosures of potential drug problems, have only exacerbated the problem, imposing more barriers to testing and marketing drugs in a cost-effective way. The climate also generates physician and patient distrust, making it more difficult to reach the necessary quality and patient volume required for reliable trials. Thus the issue of money, time, and resources is getting progressively more difficult to solve.

The fact is that there are solutions that have not been tapped to get drugs to market faster, cheaper, and better—and, in the process, to expand benefits to more patients and involve more physicians in the research process. ICLOPS provides a mechanism to achieve this. With a small enhancement of ICLOPS' existing practical services to physician practices, it is possible to make participation in trials an opportunity for more patients from a broader array of practices.

Every technology and process proposed in this paper is available now, in the current environment of physician practices, and without any additional work for physicians. Furthermore, the solutions we propose are designed to engage patients in clinical trials in the long run, reducing not only the initial solicitation of patients into trials, but to dramatically reduce the attrition rate and increase trial effectiveness.

ICLOPS is a company that analyzes physician practice data to drive targeted communications to patients. The communications increase revenue and reduce malpractice risk for physician practices by ensuring better follow-up care, especially for chronic disease patients; improve patient management of their health; and increase patient satisfaction with physician services.

The Current Clinical Trial Enrollment Environment

Most pharmaceutical companies have off-loaded the process of clinical trial management to intermediary clinical research enterprises, focusing company efforts instead on overseeing the initial research, manufacture, marketing and sales of drugs. But the entire research-to-market cycle is still the responsibility of the pharmaceutical firm, and its cost. Therefore it is not meaningful to distinguish specific roles in the process of generating physician and patient participation in clinical trials, and we do not do this in the subsequent discussion.

The actual process of enrolling patients in clinical trials is relatively straightforward. First there is a method to get physicians to participate in the trial process, and then there is a method to enroll patients. Unfortunately, the methods used in each case are limited.

Physicians not associated with major academic institutions are either not able or are not willing to participate in clinical trials, as a general rule. This is because, first, there are additional requirements for the practice that the practice does not believe it can meet, or has tried and failed in the past. Physician practices are not designed to pro-actively manage patients; they are, essentially, driven by patient-initiated transactions and visits. They frequently have almost no ability to collect data on patients, track patient listings, or manage the additional work to solicit patients. This is true for not only small, independent practices, but often of large multi-specialty groups. Finally, if a physician is not actually participating in the trial and receiving financial benefit, he or she is unwilling to enroll and thereby “lose” patients to another physician who is participating.

The networks of clinical research organizations usually consist of a limited number of trusted physician practices that have participated in enough trials to be familiar with the requirements, and have a high enough volume of patients to make it feasible. They are usually associated with academic medical centers, so that there is an additional infrastructure available to finance and support patient solicitation. The dependence on this kind of network

to support clinical trials is limiting. It is difficult, using the same physician network repeatedly, to generate enough new patients to expand clinical trials, or in subsequent marketing efforts, provide familiarity of the drug to independent physicians. It also precludes testing of the drug in the 'general' population of patients, to determine how the drug will be used and its effects in the mainstream population—not those relying on academic medical centers. Finally, it creates a rationing of clinical trials to a small number of trained physicians, making it problematic to have simultaneous trials.

Another shortfall to the current methods used to find clinical trial patients is the use of advertisement. Because the patients of physicians in networks cannot always be identified by condition, or because there are not enough of them, it is necessary for clinical research organizations to cast a larger net to find patients. They do this, primarily, through advertising in newspapers, or using lists to direct mail to potential subjects.

Using advertising has obvious shortfalls. It requires that patients with certain conditions discover the ad, and then take positive action to enroll, without involving their physicians. There is inadequate targeting of patients, except for rudimentary identification of patients from direct mail listings that rely on self-supplied information gleaned from surveys. The cost-benefit ratio of these efforts is very high.

The results of the current process are high expense, and most important, a critical failure of clinical trials to achieve volume and timeliness goals in a way that satisfies the public need. Relationships with independent prescribing physicians are, at a minimum, not improved.

ICLOPS' Services: An Avenue for Faster, Cheaper, and Better Clinical Trials

ICLOPS services make it easier for physicians to increase clinical volume and revenues from existing patients and to generate new services. ICLOPS analyses identify patients by conditions, procedures, age, and gender, assisting physicians in managing existing patients with chronic diseases and ensuring frequent follow-up. Most important, the ICLOPS services are completely integrated into physician practices, building on existing systems and processes, and cause no additional work for the practice.

The analysis and patient communications are combined in a package of services called the ICLOPS Clinical Toolset. The ICLOPS Clinical Toolset is customized to an individual practice, regardless of specialty, so that it allows the practice to track and communicate with patients with specific conditions according to practice needs.

Regardless of scope, the ICLOPS Clinical Toolset has several key components:

- ICLOPS uses billing data for analyses, which is always available from the practice as a core set. This can be supplemented by clinical and external data, if available. ICLOPS can work with any billing or practice management system.
- ICLOPS does all the work of preparing the data extract and creating the analysis database, so there is no burden on the practice. The individual practice data is kept separately in the ICLOPS data architecture, but is standardized to allow analyses of data across all clients.
- ICLOPS analyzes data to perform key clinical tests for the practice. These include:
 - A profile of practice patients, volume, diagnoses, procedures and visits, and trends for new visits or existing services;
 - Disease registries of patients, by specialty;
 - Monitoring of visit frequency and screening for patients in the registries, to trigger letters from the physician to specific patients that communicate treatment standards, request return visits, and enlist patients in further health efforts;

- Identification of potential critical failures of patient follow-up, for patients with urgent diagnoses who did not return to the office, to initiate follow-up;
- Targeted communications with patients for diagnostic tests appropriate to age, sex, and condition;
- From each analysis, ICLOPS prepares patient-specific letters signed by their physicians to initiate action by the patient.
- ICLOPS tracks the results of the communication and subsequent visit data, capturing patient responses to the initial letters. These are filed in patient charts.

The ICLOPS Clinical Toolset focuses on four targeted patient groups in the first phase of Communications, to address specific patient compliance issues. These are patients who are behind schedule in office visits, require diagnostic tests, need comprehensive visits, or should be called back to discuss new treatments or risk factors for their conditions.

The expansion of the ICLOPS Clinical Toolset to incorporate clinical trial enrollment is an easy process and provides important benefits to the timeliness, cost, and quality of the enrollment process. There are four key concepts to the expansion:

- INTEGRATE clinical trial enrollment process into the operations of the practice through the standard ICLOPS analyses and targeted communications
- IDENTIFY patients for clinical trials by clinical criteria such as diagnoses, visit and procedure history, age, and sex
- COMMUNICATE with patients by letters, requesting consideration of enrollment in the trial and an office visit to discuss options
- TRACK the results of communications

Providing these features improve the potential for physicians to voluntarily and effectively participate in trials, enroll higher numbers of patients, and provide the necessary services to ensure the effectiveness of the trial.

Getting More Physicians to Enroll Patients

Physician participation in clinical trials are restricted because there are no incentives to participate—in fact, there are disincentives because of the potential loss of patients. ICLOPS can enable physicians to refer patients for clinical research projects by providing the tools for enrollment, ensuring patient regular visits and eventual returns, and providing other patient tracking systems.

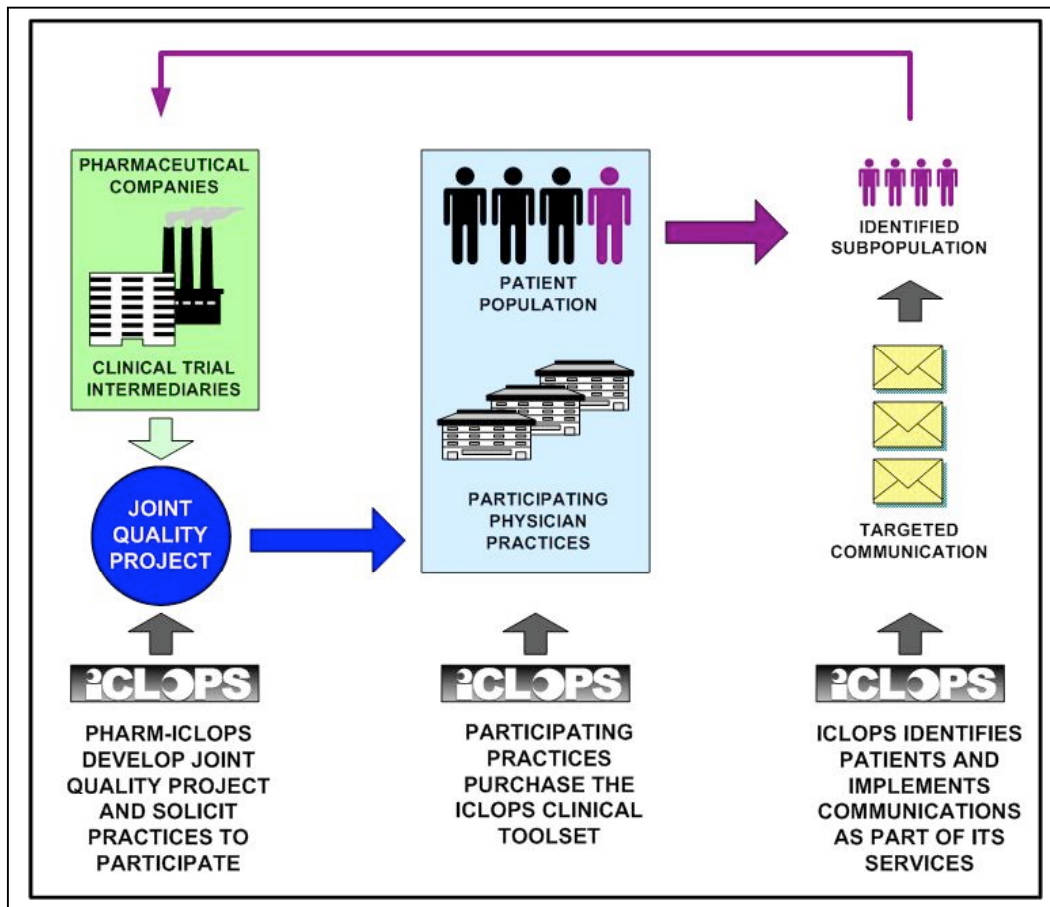
If physicians could receive maintain patient continuity, and had the tools to identify and enroll patients clinical research, it would be an advantage to primary care physicians who would like to enhance their reputation in the community and provide more options for their patients. These advantages build on the financial benefits already inherent in the ICLOPS Clinical Toolset, and make clinical research a feasible option to add.

Why would physicians consider the ICLOPS Clinical Toolset with clinical research participation? The joint benefits to the practice are clear:

- It increases clinical volume and revenue associated with existing patients
- It implements actions to grow the practice with new services and patients
- It engages patients in care and improves satisfaction
- Physicians will be forced to analyze quality by payers (pay-for-performance), and the ICLOPS Clinical Toolset is a tool for both measuring and improving quality
- Malpractice carriers want evidence of risk management activities, which the Toolset provides
- They will allow this as an easy outgrowth of other activities benefiting the practice
- It improves the image of the practice
- Physicians often have a desire to help the advancement of medicine
- Clinical Trial enrollment will be part of the broader process increasing patient involvement, choice and responsibility in the ICLOPS Clinical Toolset

Implementing The Clinical Trial Enrollment With ICLOPS

Using the ICLOPS Clinical Toolset for solicitation of patients into clinical research studies is a simple process. Pharmaceutical companies have a marketing presence in smaller physician practices that can assist in marketing the ICLOPS Clinical Toolset. After that, the identification of a specific trial, and its conditions, must become part of the patient identification criteria in ICLOPS analyses. The diagram below depicts how this can work.



A byproduct of the process for Pharmaceutical firms and Clinical Research Organizations is that ICLOPS identifies the potential population of patients for trials, and can also be used to manage communications between the physician and patient as part of the trial. These can include expectations and descriptions of the trial, tracking of visits, and tracking of physician enrollment of patients.

Summary of Advantages for the Clinical Research Industry

ICLOPS offers clinical research firms and pharmaceutical companies an option to increase involvement of both physicians and patients in clinical trials with present technology. Unlike other attempts to induce enrollment, ICLOPS can bring new physicians into the process positively, providing the tools necessary to expand the number of patients.

By incorporating clinical trial enrollment in the ICLOPS Clinical Toolset, ICLOPS transforms the process of clinical trial enrollment for patients and physicians, and potentially the industry.

The benefits are easy to summarize:

- Faster, better, cheaper clinical trials by reducing the cost and complexity of the initial enrollment process
- Creation of partnership with physicians rather than vendor relationships
- Preparation of patients for participation in trials
- Helping physicians better understand and support processes of clinical trials

Comments Welcome

ICLOPS encourages discussion and comments of the statements in this White Paper. Please contact Thomas Dent, MD, (312) 255-8421. Visit our website at www.ICLOPS.com.