



Electronic Patient Identification

David Haddick of KDH Systems, Inc discusses a new method of identifying patients for clinical trials

THE NEED FOR CHANGE

Recruiting patients today for clinical trials is a high-touch, high-cost business with many players and no economy of scale. Clinical trials are the gateway to revenue for the pharmaceutical, medical device and biotech industries, as pharmaceutical companies anticipate losing 33 per cent of their revenue in the next few years due to generics and drug patent expiry. Spending on R&D has grown by 37 per cent, from \$51 billion in 2005 to \$70 billion in 2009, while the number of new drug applications has dropped. It is clear that the development process must work faster and ensure that no product fails for lack of test subjects.

On average, difficulties in patient enrolment delay 81 per cent of all clinical trials from one to six months, costing pharmaceutical companies as much as \$8 million each day (1). In addition, patient recruiting in 2009 will cost approximately \$16 billion of the \$70 billion to be spent on R&D, and require an average of 26 per cent of the time required for each trial. Recruiting reimbursement paid by the pharma industry to investigators ranges from \$1,500 to over \$10,000 per patient for trials requiring patients who are hard to locate. Existing methods of finding patient candidates include

consumer market research, advertising and physician referrals – methods that are not meeting the needs for drug and medical device development and innovation.

ELECTRONIC PATIENT IDENTIFICATION: A BETTER WAY

Patient screening is still primarily a manual task of filtering through large numbers of unqualified patients, compounding the inefficiency of the recruiting process and causing delays or trial failure. Furthermore, using only these methods, “the criteria patients must meet for trials have reached the point that it is impossible to find a significant number of patients at a moderate number of sites” (2).

Electronic patient identification (EPI) provides a method that can access the existing untapped resource of more than one billion annual hospital visits worldwide, and to automate the screening of this population to identify previously unavailable, precisely matched candidates for clinical trial recruiting. No current methods offer the level of automation or the scale of EPI and its capability to identify the numbers of previously unavailable patients in real-time.



EPI BENEFITS ALL STAKEHOLDERS

EPI represents a win-win opportunity for clinical trial sponsors, patients and providers. Using EPI, clinical trial sponsors can easily establish unique individualised networks of trial sites, without going through the efforts of locating uncommitted patient populations. Sponsors can also add or delete trial sites from their networks based on changing needs of their trials.

Hospitals can develop a new, dependable revenue source and make clinical trials a predictable, top line contributor, while improving their payor mix. Hospitals using EPI will be able to attract more principal investigators, allowing opportunities to raise their image in their respective communities. Physicians can have access to more treatment options for their patients, and more patients will be able to take advantage of a range of additional treatments – in some cases even life saving ones.

GETTING EPI RIGHT ISN'T EASY

EPI takes advantage of existing electronic information systems in hospitals, clinics and other provider locations in order to create a reliable source of qualified subjects that can be interviewed in person at a time when treatment options still exist. EPI requires a secure software platform that is fully HIPAA compliant and that has a high degree of automation for identifying candidates for concurrent trials. Since the number of clinical trials at any time is well in excess of generally available populations, the ideal platform will be able to simultaneously recruit for an unlimited number of trials and yet deliver the most qualified patient to the most appropriate trial. Further efficiencies of scale in the EPI environment result from the principal investigators' ability to supervise remote sites and participate in enrolment decisions.

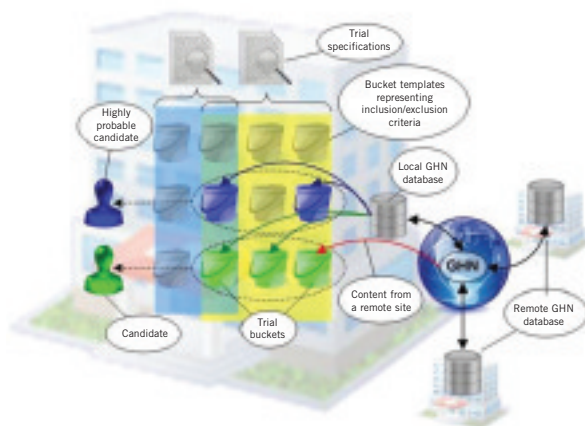
The barriers that EPI must overcome to be sustainable in the hospital environment are significant – and not solely because of the technology. Hospital IT departments are chronically underfunded and often operate at their limits. As a result of the American Recovery and Reinvestment Act (3), the IT workload situation in US hospitals has become acute thanks to the financial incentive offered to hospitals that upgrade electronic medical record systems by 2011. Other countries have their own EMR initiatives that affect the hospital IT support staff. Successful EPI systems will require minimal setup support from the IT staff, no ongoing IT involvement and will not disrupt the operations of any legacy systems.

Table 1: The NIH registry of clinical trials lists numerous clinical trials that are now recruiting or planning to recruit that could benefit from EPI

	March 2008	June 2009	Increase
Phase II	8,666	9,596	10.7 per cent
Phase III	5,365	5,757	7.3 per cent
Phase IV	6,013	6,793	13.0 per cent
Total ongoing	20,044	22,146	10.5 per cent

Each trial site also requires local autonomy so that it can automatically notify the attending physician and the principal investigator of an eligible patient, order additional screening

Figure 1: Multivariate screening



tests, prepare enrolment forms and arrange online collaborations with researchers – all according to local Institutional Research Board approved protocols. As a further benefit, a successful EPI system may eliminate the need to obtain a waiver of informed consent from each local Institutional Review Board, since researchers are provided with de-identified medical records from pre-screened and well-qualified patients, only.

A WALK THROUGH AN EPI SOLUTION

The EPI process involves loading the protocol criteria for each trial into the network of local systems, including eligibilities, inclusion/exclusion, demographics, and so on. These criteria are grouped according to medical and functional areas that are then used to sort patients into categories matching related groups of trials. When statistical thresholds are reached for any patient, the local agents will make the most accurate match to any of the simultaneous trial protocols. The details of this process are outlined in Figure 1.

Patient information is gathered and screened progressively in real-time, including all relevant updated lab data and other information as soon as it is accessible, automatically filtering and matching patients accordingly. This detailed electronic screening reduces false positives, paperwork and time, and identifies hard-to-find candidates for trials of more complex protocol indications. The critical difference in this approach is that the system actually filters the patient information in real-time from the relevant sources without requiring data mining of electronic medical records (EMR) databases.

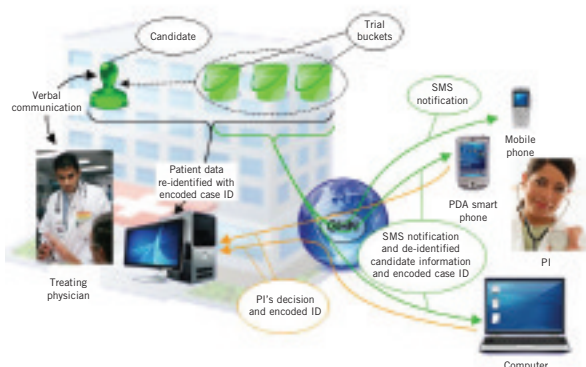
Patient information is gathered in real-time through hospital HL7 messages, specific database queries, XML document queries and DICOM reports. Patient data representing lab results, radiology reports and other patient visit data are grouped according to common factors based on the pre-loaded trial protocols. A well-qualified patient is identified from a probabilistic evaluation of the groupings, even in the absence of complete data.

The exemplar EPI system provides software agents that break down the process of identifying and matching patients to trial

Table 2: Optimisation according to increasing cost/time levels

Level I: Local matching – matching criteria for eligible candidate, including local patient history, is found at local site to complete a match
Level II: Network matching – additional historical criteria needed at several sites throughout the hospital network to find missing information for the local candidate, required to refine or confirm match(es)
Level III: Contacting primary care providers or specialists to request further explanation on information that currently exists about potential candidate(s)
Level IV: Additional requests for tests or information not currently available to determine if matching criteria is present

Figure 2: Enrolment notification and collaboration



criteria into small steps, which follow the various pathways needed to find relevant information depending on the unique characteristics of individual patients. Initially, when the requirements for a clinical trial are loaded into the network of collaborating sites, trial analysis agents at every location analyse the trial's requirements, and incorporate them into groups of common factors representing multiple trials at each hospital.

Patient classification agents continuously update their current census of patients according to their medical conditions, diagnostic tests and treatments as results become available. Then other agents compare the desired common factors with the patient classifications or groups until the search field is narrowed to a few patients for in-depth matching. When an agent finds sufficient congruence between patients and trials at

About the author



CEO and co-founder of KDH Systems, **David Haddick** has 25 years' experience designing products in association with and for physicians, primarily in the field of medical imaging. While Vice President of Engineering for Dunn Instruments he produced a number of patented products, subsequently licensed by Fuji Medical, Japan. He then founded his own successful consulting practice which, for over 10 years, distributed a variety of US and European imaging products in Japan, and also developed and sold his own system of medical imaging cameras. Prior to founding KDH, David was Product Manager for CardioMatch diagnostic software for cardiology, and was instrumental in initiating and directing clinical trials at leading medical institutions worldwide. He holds a BSEE degree from the University of California, Berkeley.

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or above the required statistical threshold, the case selector agent performs a final evaluation for the best fit among the possible clinical trials, and submits its findings to the researchers via their desired notification protocols.

Relevant patient data from multiple visits is maintained according to their groupings in order to expedite the future matching processes. This data is combined with any updated information developed in future visits and matched against all trials that are recruiting at that time. If a potential match is identified, but additional information about a candidate is required, another level of automated intelligence that weighs the cost and time required to gather any necessary additional information, and efficiently optimises the matching process.

Once the matching is complete, PIs or CRAs are automatically notified by their method of choice regarding the availability of qualified patients. The PI or CRA then consults with the attending or primary care physician to enrol each patient locally using pre-determined consent forms that can be customised and printed (see Figure 2).

SECURITY IN AN EPI WORLD

The latest technology allows secure data communication and eliminates additional expenses normally required for security features of traditional, physically secure networks without requiring VPN or other secure pipes. All patient data transferred across the trial site network is de-identified and encapsulated into secure envelopes with full authentication. Besides HIPAA compliance, this level of security ensures that patient data sent through the open internet is protected even if the users' computers are hacked successfully.

CONCLUSION

At a time when new drugs and devices are needed urgently to solve health problems and improve quality of care, the need for cost and time efficiency in getting these modalities to market has never been greater. EPI automates processes that are currently outmoded for clinical trial candidate identification, moving away from costly, haphazard, unreliable processes and results in favour of an efficient, secure, real-time electronic method, accessing millions of previously unavailable candidates and streamlining notification immediately to authenticated users.

EPI benefits principal investigators and other physicians by enabling the enrolment of more patients at a faster rate; hospitals benefit by receiving reliable reimbursement for more patients participating in clinical trials, and pharmaceutical companies are able to reduce their patient recruitment costs dramatically and accelerate significantly the timeline for moving their drugs to the market. Patients also benefit by gaining more timely access to clinical trials as well as ultimately having access to improved quality of care.

References

1. Center Watch
2. *Streamlining Clinical Trials*, 2008 Cutting Edge Information
3. American Recovery and Reinvestment Act, 2009