Innovative Electronic Patient Identification System:
Reducing burden while improving site selection and study forecasts.
In recent years, the clinical development function has been adopting software tools to improve productivity and speed study timelines. Yet, there are still pockets of opportunity for manual tasks to be automated and for paperwork to be digitised.

As a case in point, one global pharmaceutical company recently began using an electronic system for identifying patients who may be eligible to participate in an extensive clinical program comprised of dozens of protocols. The system can be customised to identify and “reserve” prospective subjects for Phase III trials in any therapeutic area.

The business challenge:

**Heavy manual burden in estimating recruitment**

Study teams confront one of the most challenging aspects of clinical trials well before the trial even begins: estimating the number of patients that can be recruited, by site and country. Typically, they go about this by asking study monitors to perform a pre-study evaluation of sites under consideration. The monitors canvas investigator sites, gather estimates of the number of potential patients, enter the details into a spreadsheet and then fax the information into the study team. Monitors’ individual spreadsheets then need to be consolidated to provide an overall look at patient availability.

Because busy monitors have little time for this burdensome process, they don’t always gather information as thoroughly as they might. When that is the case, the number of available patients in certain areas can be drastically under reported, and sponsors may consequently select more sites than they really need.

As an Almac Clinical Technologies Design Manager was chatting with a sponsor’s IRT coordinator prior to the start of a conference call to discuss an IRT build, she casually asked a question about the sponsor’s process for estimating patient counts. The conversation brought out the sponsor’s concerns about the manual steps involved, including the fact that monitors had been struggling to keep up with the demands of the manual process and the paperwork involved.
In response to the sponsor’s need for greater efficiency in identifying prospective participant counts from sites, Almac developed a customised, pre-screening patient identification system. Using the tool, investigators from around the world report (via a web interface or a voice response system) on the number and type of patients in their care who could be candidates for any study across as many as 40 protocols. Sites are reimbursed for their efforts.

The system consolidates information on potential participants by site all in one place, allowing the sponsor to:

• Create global reports on the number of potentially eligible patients by site, by inclusion/exclusion criteria
• Select sites and develop trial forecasts based on global patient availability
• Make electronic “reservations” for patients, preliminarily matching patients to specific studies

The patient identification system can be linked to Almac’s Interactive Response Technology (IRT) - IXRS®, to provide an update on how patients progressed in the study for which they were proposed. This linkage also helps sponsors monitor sites’ effectiveness in reviewing their patient charts and determine site reimbursement when applicable.

The Almac solution:
An electronic patient identification system

The client results:
Quick assessment of potential patient counts

Sites have now begun to use the system, and the sponsor’s clinical team—and most especially monitors—are impressed with its functionality. The clinical team appreciates the real-time reports it provides, and the monitors are delighted to be relieved of their time-consuming data collection and manual reporting responsibilities.

In the long-term, the sponsor is expecting that as more complete information will be coming directly from investigators, the study team will have counts of potential patients, by site, months in advance of each study go-live. Ultimately, this electronic reporting process will:

• Support more accurate trial forecasts
• Improve site selection
• Promote faster study start up
• Reduce the clerical burden on monitors and the study team

A chance mention of the sponsor’s manual process has thus produced a solution with far-reaching implications for time and cost savings on dozens of upcoming studies for the sponsor.
GET IN TOUCH

UK
Almac Group
(Global Headquarters)
20 Seagoe Industrial Estate
Craigavon
BT63 5PW
United Kingdom
clinicaltech@almacgroup.com
+44 28 3835 2121

US
Almac Group
(US Headquarters)
25 Fretz Road
Souderton
PA 18964
United States of America
clinicaltech@almacgroup.com
+1 215 660 8500

SINGAPORE
Almac Pharmaceutical Services Pte. Ltd.
9 Changi South Street 3
#01-01 Freight Links Building
Singapore 486361
clinicaltech@almacgroup.com
+65 6309 0720