Description

Carefully managing communication with prospective clinical trial patients in terms of key messages, language and cultural considerations, and format/media will serve to directly and effectively address concerns and misconceptions that are contributing to low participation rates. Currently, communication is not managed and will take as many forms as there are sites and health care providers recruiting patients, and is limited to the skills of recruiting staff at each site.

Oncology institutions utilize EHR/EMR software to manage patient records and workflow tasks. A Patient Portal is an extension of the EHR/EMR that provides a frequently visited and highly credible web-based communication tool with patients, in a secure, online environment. A Portal presents provider-defined aspects of the medical record to patients, but importantly also serves as a two-way communication platform as well as a repository for various media and online tools that can be shared with patients individually or in segments (e.g., by language preference) in order to very carefully target the communication. It is a tool that is regularly visited by patients as they use it to manage interactions with their physician (e.g., set appointments). It is credible as it is an extension of the medical record and patients consider materials shared as authored or endorsed by their own provider.

To increase participation rates and directly address key patient barriers, Study Committees have opportunity to take control of the conversation with patients and centrally prepare resources that can be delivered in a targeted fashion to appropriate prospects (as defined by demographic and clinical parameters in their chart), in a recruitment campaign with measured patient response, in a trusted, secure environment that supports direct and efficient patient communication with providers in order to permit follow-up and a managed process concluding in agreement to participate.

Why will it work? Why is it viable?

Aside from the obvious of offering a mechanism to extend an electronic invitation to participate in a clinical trial following a criteria-based search of an institutional EHR/EMR in order to create greater awareness amongst eligible patients, a Patient Portal can be utilized to disseminate rich educational media content to prospective patients that is developed/approved centrally by the Study Committee. This ensures that the message is carefully controlled and managed, and the material addresses the documented barriers to patient participation. This new means to communicate will be more effective as 1.) it can be carefully architected to address specific known misconceptions, 2.) it can be designed to reflect cultural biases and preferences, and can be provided in any language, 3.) it can be provided in flexible formats for delivery to suit different learning styles (e.g., video, text, audio) with the ability for patients to review the material at their own pace, and 4.) patients will be able to efficiently follow-up online with their provider with remaining questions and concerns in order to satisfy themselves that they should participate. Control remains with providers to select which patients will receive the information, and patient participation in review of the material can be measured and tracked, with reminders and prompts built into the deployment. Additionally, relieving physicians and staff of responsibility for education will increase their participation rate in recruiting patients.

How will you do it?

Many EHR/EMR commercial software has Patient Portal capability, and failing this there are currently marketed HIPAA-compliant Portals available that can interface with any institutional software.

How does it work?

Providers/Institutions choose which patients will be provided access to a Patient Portal. Patients are provided login credentials and are able to access their record over the Internet and participate in two-way communication. Providers choose what information to share with patients, and control

which patients are invited to participate in trials, as well as what information will be shared with them within their online environment. Study Committees will support recruiting institutions with material relevant to their study that is shared via the Portal.

What does it look like?

A Patient Portal should be a hosted solution that is accessed via patients through a secure mechanism. It should be hardened for health information, HIPAA-compliant and leave no record locally on a patient's computer.

How will you implement it? Who will be involved (stakeholders)?

A group representing the study sponsor and research communities, oncology institutions, and provider and patient representatives should be formed in order to prepare a needs assessment/feature requirements/implementation and support requirements document and an RFP. Vendor selection would follow, which may involve the oncology institution EHR/EMR systems market share leader and their Portal solution, or a software agnostic Portal that can interface to any existing system.

Where will you implement it?

An obvious starting point for a managed/funded deployment is to implement the solution at oncology treatment centers to support with therapeutics trial patient recruitment. Eventually Patient Portal technology will naturally become part of the tools utilized by PCPs and a similar approach can be utilized for prevention trials.

How much will it cost to create the solution (an estimation)?

Different vendors will charge different amounts for their solutions, but an estimate is several thousand dollars per month, per institution. Any software development work will be incremental to this licensing and support fee. However, Institutions and providers may wish to deploy a Portal regardless (and perhaps co-fund) due to the financial incentives created by the technology; it is a requirement of Stage 2 of the federal meaningful use incentive program, and Portals for administration tasks such as patient registration or appointment management can be cost saving for a practice. A budget will also be required to prepare patient education and other recruitment materials, and may be funded by study sponsors. It is reasonable to conclude that there will be opportunity to utilize many of the materials over multiple studies when common non-study specific barriers are being addressed. Existing resources available will reduce this budget.

How much will it cost to implement the solution (an estimation)?

Software vendors may or may not charge fees for one-time services to implement the solution. With selection of one vendor across a large number of institutions there will be significant bargaining power to minimize implementation fees.

How many people will be impacted?

A Portal deployment will impact many of the patients seen at oncology institutions, however patient participation is controlled by the institution/providers. The Portal is an extension of the EHR/EMR so various staff and providers in a role-dependent fashion will interact differently with patients following implementation, however it is not a major workflow overhaul as was likely the original EHR/EMR implementation.

How long will it take to create the proposed solution?

It is estimated that the RFP process will take 6-12 months. Patient education material preparation will take a similar amount of time, and can take place concurrent to this process. Following vendor selection the pace of implementation can be managed by the steering committee but should be relatively efficient as there are minimal workflow changes with the project. Patient technology training can be provided in an efficient online manner.