1 Patient Centric Recruitment; a CRO's perspective

1.1 Reasons for Change

It has all been said before: Over 95% of the clinical studies fail to meet their original time lines and budgets[1] and that one day of delay could cost a sponsor $1.6 million on averaged lost revenue.[2]

Between 2006 and 2016 the global spending on drug development will grow from $108 billion to over $148 billion.[3] Clinical trials account for 45% to 75% of this cost[4] and in 2012 the life sciences industry was already spending $1.2 billion on patient recruitment alone![5]

Difficulties with patient recruitment are the main reasons for delay. It is obvious that the focus of clinical trial processes and procedures has to shift to the needs, wishes and concerns of the patient. It has to be more about the patient's experience before, during and after trial conduct!

1.2 A Change of Attitude

In any company, processes and procedures are focused on what the owner of these needs to accomplish and any third party involved is just a mere direct object; a means to an end. This applies to any industry and ours is no different.

Obviously there are limitations to what we can demand from these third parties and if we demand too much they will refuse further cooperation. For clinical trials, research shows that we apparently have

[1] *Tufts Center for the Study of Drug Development Impact Report 15/1"New Research from Tufts Characterizes Effectiveness and Variability of Patient Recruitment and Retention Practices", January/February 2013.*
[2] *Applied Clinical Trials, RbM Guidance Document: Ten Burning Questions about Risk-Based Study Management, January 13, 2015*
[3] *EvaluatePharma, World Preview 2014, Outlook to 2020, June 23, 2014*
[4] *http://www.pfizer.com/research/clinical_trials/phases_of_development*
[5] *Tufts CSDD, 2010 Survey of 3,516 Global Sites and 2012 survey of 48 sponsors and CROs*

reached the limits of what we can ask from patients and the only way forward is to change our attitude and look at things from a patient's point of view.

We need to communicate and cooperate more with patients about their needs, wishes and concerns. A better understanding about the patient will help us to tweak our processes and procedures to accomplish a better cooperation; a true partnership.

Patient centricity is about a change of attitude and getting patients involved, engaged and empowered.

2 Our Perspective on Patient Centricity

2.1 About Link2Trials

Link2Trials is a contract research organization offering subject/patient recruitment, preselection and retention services for clinical trials since 2007. Being specialized in recruitment services, Link2Trials is always challenged to find the best way to the hearts and minds of patients.

This is why from the first day we started offering our services to the life sciences industry and long before anyone talked about patient centricity, we were already focused on how to continuously improve the patient's experience with recruitment for clinical trials.

This focus is essential to the effectiveness and quality of our services. Therefore it is incorporated in anything we do and in the software solutions we have developed to support our activities.

We truly believe that patients need to be involved, engaged and empowered, and with this white paper we would like to provide insight on how Link2Trials integrates patient centricity in patient recruitment.

2.2 Involve!

Link2Trials motivates patients to get involved by interactively informing them about currently running and upcoming trials through traditional and/or digital media channels favored by our targeted audience. A cross-media approach ensures that our messaging goes out to a large and targeted audience.

The content of our message is defined by and compliant with the trial protocol and the IRB/IEC guidelines, but how we communicate our message and through which channels very much depend on the type of patients we are looking for.

Good examples are our Facebook pages for patients. On these pages we publish information about the trials for which patients are sought. Furthermore, we also interact with our followers about general clinical trial news and motivate them to actively spread the news.

Alongside media channels like magazines, newspapers, Facebook, Twitter, etc., Link2Trials has set-up special patient recruitment sites for each country we are recruiting for. Here patients will find extensive general information about clinical trials, safety, video's about different procedures and more.

Additionally, optional study specific portals and webpages present all the available study information, informational and Informed Consent Form videos, study updates, relevant links to patient associations & communities etc. Through these portals and webpages study teams can also share relevant updates on the study or nice to haves such as recipes for diabetes patients.

2.3 Engage!

A potential patient can truly engage by registering on our patient recruitment sites and enter his profile, including all health data that they are willing to share and the preferred days and times for contacts and visits.

Based on location, personal and health data a patient can pick and choose from the studies that are published on the recruitment site, and based on that same information they will get notifications about studies that are recruiting.

After they have made their choice, further questionnaires will make it clear if they are initially eligible for the trial of choice. If this is the case then someone from the site will contact them to schedule a first visit.

2.4 Empower!

The first step to empowerment is that the potential patient no longer depends on their physician to get the study information they are seeking. Today our patient recruitment sites enable them to select a trial based on their personal health profile and they can also set their preferred days and times for future visits.

Our Facebook pages even take empowerment a step further since it provides an opportunity to respond on the information published by Link2Trials and interact with our team and other followers of these pages.

In the future Link2Trials will empower the patient even more by providing functionality that enhances his user experience before and during trial enrollment.

3 Patient centricity behind the scenes

3.1 A Fundament for Software Solutions

Patient centricity has always been a key priority for Link2Trails. It shows in the way we share information and interact with potential patients. All information we publish digitally is web based and can be accessed by both patient and site personnel alike from anywhere, any time and through any (mobile) device.

It also shows in the functionality of the Patient Recruitment & Retention software solution we have developed for our recruitment projects. Our clients can access and use this software solution through our SaaS (Software as a Service) offering, and this option enables them to boost the patient centricity of their clinical trials almost immediately and against limited costs.

Our software solution allows for a quick and easy set-up of recruitment projects. You can enter basic trial specifications plus selection criteria and add the trial information you would like to publish.

You can add additional in- and exclusion criteria in an unlimited number of AND/OR relations, and if that is not sufficient, the Questionnaire Builder will help to narrow down your target group even more.

3.2 Minimize Early Drop-out Rates

Misconceptions, wrong expectations and excessive burden are the main reasons why patients drop out during study conduct. Early drop-out rates are 30% on average[6] and they have a very negative impact on site level time lines. At these rates drop-outs can also disrupt the overall planning and logistics of the trial.

To minimize the risks of early drop-outs the quality of trial messages can be enriched by adding extra information such as pictures, slide shows, presentations and (ICF-) video's.

The trial information you enter will help patients to get a better understanding of the trial, what to expect during trial conduct and what their role will be. The criteria you enter will speed up and fine tune the selection process, thus limiting the time the patient needs to spend on figuring out if he is eligible or not.

[6] Tufts Center for the Study of Drug Development (2008). Growing protocol design complexity stresses investigators, volunteers. Impact Report Vol.10, No.1, Jan/Feb.

3.3 Limit Travel Time

Our software solution also includes a map based scheduling tool that can handle both groups and individual patients. Schedule templates for activity, call and visit cycles can also be built.

The selected patients are plotted on a map, thus it is now very easy to understand where everyone is located and what estimated travel efforts can be expected. Moreover it will help to select the patients nearest to the site location and at the same time limit travel time for the patient.

3.4 Schedule & Remind

The scheduling templates will help to plan future calls, activities and visits based on the cycles you desire. It will also help to adjust the schedule to the patient's limitations and at the same time respect the required intervals.

The Reminder & Retention tool enables you to create text messaging and email templates, to remind patients about upcoming activities they are involved in. The system will send out these reminders and it is proven that this mechanism has a tremendous positive effect on retention.

The above functionality not only supports site personnel to manage patients selected for the trial, but also helps patients to stay involved and engaged in the trial.

4 Continuous Improvements

For Link2Trials improving the patient centricity of our services and software solutions is a continuous process. In the near future we will add more functionality to empower the patient during recruitment and clinical trial conduct.

The recruitment team may see advanced functionality which will visualize (in numbers and on a map) what the potential effect of a specific selection criterion is. Such functionality could help to reduce the number of patients that are invited for a first visit but are excluded after that.

The patient may see map based functions that will provide insight about which trials are in close proximity to their location. A personal trial schedule might be implemented, where the patient can add events that the site team can take into account when scheduling trial activities for him. A chat function to communicate about the trial or scheduled activities could also be considered.

When, what and how will very much depend upon the feedback we get from our audience.
In the end it is not for nothing that this is called patient centricity!