THE PAIN CLINIC

2018

Partnerships in Clinical Trials Symposium

A problem solving forum for all aspects of running clinical trials.

Led by Kate O'Brien with thanks to Sammy Ainsworth, Eamonn O'Brien and Vivienne Van De Walle for their contribution.

THE PAIN CLINIC

PARTNERSHIPS IN CLINICAL TRIALS SYMPOSIUM

INTRODUCTION

The concept behind this initiative was to identify some of the issues that face different areas of the industry when developing, setting up and conducting clinical trials. With the wealth of experience available at the PCT symposium it was then the task to develop possible solutions to these. Discussions prior to the event with patients, site staff, CRAs and pharmaceutical companies highlighted a number of areas to address. These were then categorized under five headings.

PATIENT ENGAGEMENT

- Lack of research awareness
- The Patient Information Leaflet
- Unaware of available trials
- Can't take time off work/school
- No local site
- Travel issues

FEASIBILITIES

- Not enough details provided to enable sites to search accurately
- Lack of transparency from sites regarding workload
- No feedback if not selected

SITE PERFORMANCE

- Under recruitment
- Excessive screen failures
- Data entry out of timelines
- Slow response to data queries

TECHNOLOGY

- Inadequate training for site staff and patients
- Devices under performing
- Poor support from helpdesks

PATIENT PAYMENTS

- Patients not keen on cash payments
- Difficulties holding petty cash at site
- Trials not standardized, some pay, some don't.

The forum saw excellent participation from many delegates at the symposium. Attendees were encouraged to discuss problems and post ideas for solutions.

SOLUTIONS

PATIENT ENGAGEMENT

LACK OF RESEARCH AWARENESS
Develop a research registry for patients interested in participating in clinical trials. (MEDICOLLECT, NIHR)
Collect positive comments from trial participants and display these to promote trial participation
Look at a community outreach
Generic information from the government

PATIENT INFORMATION LEAFLET
Involve patient groups in design (NIHR)
Use a professional company (LIFE HEALTHCARE)
Consider health literacy, ensure that the document is formatted to enable the majority of the population to read and understand.
eICF – have an interactive online document. Facility for investigator to check what patient has viewed and for patient to raise questions

UNAWARE OF AVAILABLE TRIALS
Consent to contact registries
Better/wider advertising
APP and website

DIFFICULTY TAKING TIME OFF WORK/SCHOOL
Virtual and hybrid trials. Utilise mobile technologies for remote data collection.
Home visits
Assistance with travel arrangements

NO LOCAL SITE
Concierge service to arrange travel to sites (GREENPHIRE)

TRAVEL ISSUES
Pay travel expenses
Concierge service for those patients who can't afford to wait for reimbursement (GREENPHIRE)

FEASIBILITIES

NOT ENOUGH DETAIL PROVIDED FOR ACCURATE SEARCH
Use data led solutions (DISCOVER)
Sponsor to provide more information at feasibility
Data provided to be search friendly
Sponsor could have search built to export to sites

SITES OVER OPTIMISTIC TO SECURE WORK
Assess previous recruitment history, numbers recruited and timeliness
Sites to provide evidence to support claims

SITE LACK OF TRANSPARENCY OVER WORKLOAD
Check site website for ongoing work
National registry for the industry of site information. To contain details of site facility, history of trials run, numbers recruited, ongoing trials.

NO FEEDBACK IF SITE NOT SELECTED
Sponsors to contact sites and provide individual feedback on reasons for non-selection.
Sites to be proactive in contacting Sponsors and asking for feedback

SITE PERFORMANCE

UNDER RECRUITMENT
Access site's previous performance data, check numbers recruited, targets met
Investigator engagement, is the PI available to meet with CRA, are the investigators engaged and interested during meetings?
Improve the feasibility process to ensure Sponsors are selecting quality, transparent sites
Details of five sites who consistently perform at the highest levels were available at the forum and are attached to this report

EXCESSIVE SCREEN FAILURES
Cap screen failure rate
Lower screening fee and higher randomization fee
Pre-screening assessment visit (WOODLEY)
Better Protocols to limit screen failure risk

DATA ENTRY OUT OF TIMELINES
Sites to utilize two linked screens for simultaneous data entry
Withold site payment
CRA to monitor and follow up issues with PI

SLOW TO RESPOND TO DATA QUERIES
Daily reminders
Withold site payment
Sponsor to clear resolved queries from system to ensure open queries are easily found
CRA to support site in answering queries

There are several tools available to help sites with the daily management of trials. Examples of this include the laboratory supplies caddy developed by ACM Global laboratories that makes it easier for sites to select the correct visit kit and to monitor supplies. World Courier unpack IMP shipments at site, helping to avoid temperature deviations. Companies including Oracle Health Science and Medidata and developing single platforms for data entry and trial management.

TECHNOLOGY

INADEQUATE TRAINING FOR SITE STAFF AND PATIENTS
Assess site's previous experience with systems
What provision does site have in place to support patients using mobile devices
Select vendors that provide comprehensive training
Listen to site and patient feedback on training
Vendor to provide ongoing support

DEVICES UNDER PERFORMING
Sponsor to assess positive previous performance when selecting vendor
Sponsor to provide clear details on back up plans in case of device failure
Sponsor to listen to site's feedback on device performance

HELPDESKS
Sites to report bad experiences
Sponsors/ Vendors to follow up on these reports
As above regarding communication issues with language barriers

PATIENT PAYMENTS

PATIENTS NOT KEEN ON CASH

Discussions with patients show that the majority do not like to receive cash. They have concerns over safety if carrying sums of money and feel that other payment systems are more compatible with modern life.

Utilise alternative payment system (GREENPHIRE CLINCARD)

DIFFICULTIES OVER HOLDING PETTY CASH ON SITE

If cash is the only option –

Sponsor to provide float

Pre-pay site

TRIALS ARE NOT STANDARDISED SOME PAY SOME DON'T

Sponsors to recognise that the patient's commitment and reimburse for their time, this would also assist with recruitment and retention

Sites to negotiate patient payment as part of contract discussions

CONCLUSION

The input from sites, CRAs, CROs and vendors showed that there is an appetite to identify and resolve the issues that hamper the efficient delivery of clinical trials. Disappointingly there was a lack of input from the pharmaceutical companies directly and without a willingness on their part to engage, change and improvement becomes difficult. The Pain Clinic achieved its goal in highlighting problems and pinpointing solutions.

Some of the areas of difficulty related to site performance. Available at the forum were profiles of five UK Primary Care sites who consistently perform at the highest level. The author does not work for any of these sites and received no financial incentive to include them.