PHARMACEUTICAL INDUSTRY
PROJECT MANAGEMENT GROUP
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Project Sessions

Project Sessions by PIPMG

Short and engaging Project & Portfolio Management interactive sessions with keynote speakers & expert breakout groups. Participate to engage with practitioners to advance your knowledge, expertise and network.

Project Sessions *by PIPMG* FREE virtual series will be held on the following dates:

- "Project Management experiences in the pandemic" – 22nd July @11am GMT
- "PM practice in the new normal" with keynote speaker, John Swales, AstraZeneca – 3rd September @11am GMT
- "The Clinical PM of the future" with keynote speaker, Shola Ayeni, Applied Molecular Transport - 1st October @11am GMT

Agenda

1. 11:00, Welcome and Introduction
2. 11:10, Keynote Speaker: Shola Ayeni, Applied Molecular Transport
3. 11:40 Q&As
4. 11:50 Breakout sessions
5. 12:15 Breakout feedback summaries
6. 12:30 Close

BREAKOUT SESSION QUESTION:

What impacts have you seen on clinical operations?

What are the key changes to clinical PM that we will see from now on?

BREAKOUT ROOM 1:
What impact have you seen on clinical operations?

Delays in non-Covid trials and great pressure for Covid-19 trials to deliver fast

The pandemic has had a great impact on recruitment/opening of new sites and trial conduct especially in disease areas like oncology where patients have been particularly at risk. In these cases, a protocol dependent risk-based approach for ongoing patients has been adopted, with virtual monitoring visits, virtual investigators meetings and in some cases, samples not collected to avoid site visits. New recruitment stopped and has only recently re-started.

On a CMC and drug supply point of view, there are lots of delays for non-Covid trials and enormous expectations for delivery of Covid-19 trials. In both cases the Sponsor has to take the financial burden if things are not as planned.

Increased need of working even more closely with drug supply, increasing complexity

Consideration: if there is a consistent next wave of infections, will site resources be taken away from non- Covid trials to prioritise Covid-19 activities? The CPM will need to plan for this

Approaches where nurses will be going to patients' homes adds another level of complexity in Clinical Project Management

NHS using agency personnel who have been pulling out for Covid-19 concerns is increasing sites resources pressure

BREAKOUT ROOM 1:
What are the key changes to clinical PM that we will see from now on?

Expectations that there will be a level of streamline in the clinical pipeline, from regulatory submission to reporting e.g. more virtual visits and investigators meetings, more telemedicine, looking critically at protocols to decrease, not critical interventions etc.

There will be differences in early and late phase trials, e.g. in late phase trials it will be easier to implement a reduction of interventions (less exploratory endpoints)

There will be differences between oral and other route of medications e.g. IV that cannot be delivered and administered in a home setting

Covid-19 pandemic has increased general interest for science and clinical trials, Clinical Project Management could be a career more widely of interest

BREAKOUT ROOM 2:
What impact have you seen on clinical operations?

There are two types of activities now, CRO and pharma are either doing Covid related stuff or not

If Covid related, there is a whirlwind of activities, facilitated by regulators (I.e., a degree of deregulation). In one example provided in the breakout room, changes to protocol were made (home delivery of medicines) and regulators informed after and this was praised by regulators

If not Covid related, activities are severely impacted / lots of trials are on hold now. Perception that regulators are more cautious and less hawkish for these trials than before

Level of impact on e.g., recruitment, depends on geographical location (greater impact in US/ W Europe vs India/ E Europe)

Noted that NIHR publishes a list of what would normally be a substantial amendment but no longer is due to pandemic

BREAKOUT ROOM 2:
What are the key changes to clinical PM that we will see from now on?

E-signatures will be permanent change, no one will ever object to them ever again

More remote contact of monitors with sites, e.g. site staff will show patient record virtually. However, there are challenges because can't tie down site coordinators for long periods of solid time - can't replace 8-hour visit on site where site staff can be seen for shorter periods of time

There is a transformation in the introduction of technological solutions in clinical trials across the board. In pharma, staff don't always have technology skills in outsourcing deptartments to understand technology solutions – the increased expertise in this area is likely to come (e.g. how to validate, benefit etc, the sort of questions regulators would ask)

BREAKOUT ROOM 3:
What impact have you seen on clinical operations?

ETHICS COMMITTEES
The speed in which ethics committees can respond is impacted. They could work faster but volunteer based so relying on this long term is not realistic. Good professional support exists in UK and helps committees. E.g. checking documents available and standards are met, and if a full of proportionate review required (sub vs full committee).
There is a lot of slack in the approvals process and needs a way to tighten up the timelines without inconvenience the volunteers. E.g. shortening turnaround times - but this depends on the pressure on the professional staff as they may be under resourced.
Does virtual operations speed things up? Yes but still monthly meetings and email used for discussion as it gives time to think. This also depends on country, e.g. Tunisia was all F2F between 2 people and presented in person, so in this case delays could be virtual.
HYBRID MODELS - Increasing home based, telemedicine
Budget implications on the changes in delivery
Impact on maintaining priority reviews
Data compliance
Meeting regulatory requirements
DELAYS
Delays were experienced with respiratory compound FTIH. Screening changed to be sure volunteers did not get Covid, started 1 day early and kept isolated. 1 extra overnight stay increases budget for a small company and is difficult.

BREAKOUT ROOM 3:
What are the key changes to clinical PM that we will see from now on?

People are more willing to look at change, E.g. data analytics, AI, data sharing

There armany vendors so training them all is onerous. Each wants their own training session. Needs to be addressed.

Can larger companies help smaller ones in the changes? Could help with standard templates, delegation logs, etc. Transcelerate website can help.

Seeing what is the same in all trials, share, and then focus on your differences in the right support for patients. Seen this in rare diseases where patients are much more involved and vocal.

Involving patients more. Patient centric managers. Talk to patient forums to input onto study design. E.g. worried about Quality of Life

Patient involvement in the development of protocols is very valuable to know for ethics committees. They look for this in an application.

BREAKOUT ROOM 4:
What impact have you seen on clinical operations?

Shift to remote monitoring, remote site qualification, remote site initiation etc., in absence of F2F options – acceptance and success rates/challenges of using these are variable depending on company and trial complexity. Some companies have preferred to wait until F2F options have become or will become available

Adoption of studies by NIHR has been an issue that has affected UK based sites and studies

Issues have been observed with site communications during the last seven months

Recruitment difficulties – has been challenging for existing patients and for the recruitment of new patients – patient fear of attending sites or less available resource at sites to contact patients etc due to redeployment

Expiry of IMP

Difficulties with site personnel motivation – much better to do this F2F – Less attention and engagement when doing these activities remotely

Confidentiality issues – GDPR related

Difference in medication type has had a significant impact on studies – Oncology studies involving IV administration have suffered significant delays due to site access, patient safety concerns etc vs for example tablets which can be shipped to patients direct

BREAKOUT ROOM 4:
What are the key changes to clinical PM that we will see from now on?

Travel will be reduced going forward – may see increased use of more locally based monitors and monitoring?

Long haul travel is likely to stay significantly reduced due to effectiveness of virtual technologies

When dealing with certain clients (such as university spin-offs, start-ups etc) – amalgamation of different types of project management – clinical, toxicology CMC etc based on cost grounds will probably result in increased likelihood of expanding the scope of the classical clinical PM role

Monitoring of sites will revert back to F2F going forward

Impact of Brexit – impact on UK based trials – will no doubt present both opportunities and challenges

NEXT MEETING

Data analytics and AI - is this the new Project Management?
How these techniques may affect our processes, plans, decision-making and team working

November 2020 TBC

Thank you

If you have any questions, please contact

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