Interoperability: The Top 5 Benefits and Burdens of Utilising the CRO eTMF

In the build up to *Trial Master Files Europe 2015*, Claire Mooney, TMF Lead - Process and Quality, Quintiles, spoke to Andrea Charles from Pharma IQ to take closer look at how a modern day global contract research organisation (CMO) is approaching eTMF and assess the top 5 benefits and burdens of utilising the CMO's electronic trial master files.

Pharma IQ: What key factors do you think drive the move to a robust eTMF system in the first place?

C Mooney: In today's environment, we can now do normal, everyday shopping online. When we actually go to shops we have the option of receiving the receipt via email. I am sure anyone who works with trial master files knows that TMFs can contain thousands and thousands of sheets of paper. In today's environment we cannot work like this anymore. We have to condense the amount of paper that we need to keep, thus helping the environment at the same time.

A robust eTMF system is simpler, it's easy to navigate, we have real time access anywhere in the world and we don't have to travel to the country that's holding the TMF.

Pharma IQ: What would you say are the key considerations to make when implementing an eTMF system?

C Mooney: When implementing an eTMF system it's best to look at other companies who have already implemented a well-established eTMF and look to their lessons learned. I would strongly suggest that people utilise the TMF Reference Model; it is adaptable to your company's needs. Also ensure that you are using the most up-to-date technology. Technology quickly becomes obsolete, if we use the most up-to-date technology when we have a new update our systems will allow us to move with the times.

Pharma IQ: After implementation, what would you say was your top lesson learned? And would this knowledge have impacted your initial implementation strategy?

C Mooney: The top lessons learned for us would be the engagement from the other departments within the CRO. We had lots of gaps of where we should file things but where we had no location to file it. Whether that would be from not having the right SMEs from within the department or the non-engagement from the some departments, because it's TMF/eTMF they may think it doesn't apply to them. However, engaging all the departments, bringing everyone together, detailing how important it is to have a fully robust filing system in order to house our electronic trial master files is probably one of the biggest lessons learned.

Pharma IQ: What does a typical timeline look like to achieve a full-integrated eTMF system? How would you classify the different stages in implementation?

C Mooney: A reasonable timeline for implementation of a fully robust eTMF could probably take upwards of 12 months. At Quintiles, we have implemented eTMF – our first pilot study went live in October 2010 – and we have had many challenges. We have had lots of lessons learned, whereas we are just now moving through looking at all the lessons learned that we have had over the last four years and we are currently going through an eTMF transformation.

To fully implement, I would say around about 12 months, but to have a fully robust, compliant eTMF system, it could probably take upwards of two to three years.

Pharma IQ: What do you consider to be the key implementation steps that impact eTMF inspection readiness?

C Mooney: The biggest impact on eTMF Inspection Readiness is missing documentation. One key implementation step is re-education of staff to ensure each and every person responsible to contribute to the eTMF knows what is expected of them; what needs to be filed, when it should be filed, where to file it and performing periodic and trigger related comprehensive file reviews.
This should be built into Standard Operating Procedures (SOPs) that are cross-functional which guarantee all staff members are informed and knowledgeable of helping build an Inspection Ready eTMF.

Top 5 Benefits and Burdens of Utilising the CRO eTMF:

Benefits	Burdens
No Cost to Sponsor for System Training When using the sponsor eTMF system there has to be training in place for the CRO staff in order to be able to access the sponsor system. Now, depending on the sponsor, this can either be done face-to-face, for which there obviously has to be a cost to the sponsor, or it can be done via teleconferences and videoconference which, at the same time, are a resource and a cost to the sponsor. If the sponsor uses the CRO eTMF, all of the people who are involved in compiling the eTMF are already trained.	**Learning to Navigate New System(s)** There is a little learning curve for the sponsor team members in order to be able to navigate through the CRO system. That can take a little bit of time, however it's not a huge burden
No Sponsor Resource to Provide and Maintain CRO Access When a CRO uses a sponsor eTMF system it is the sponsor's responsibility to provide the initial access, and also checking compliance for the CRO staff and to maintain that access. There may be an issue maintaining the access for the CRO staff within the sponsor system. By utilising the CRO eTMF there is no resource, and subsequently no cost to the sponsor in order to provide and maintain CRO staff access.	**Access Controlled for Sponsor Trial Team Members** Access controlled is always a good thing: that ensures that they are Part 11 compliant. In this context, in order for the sponsor trial team members to gain access to the CRO eTMF their names have to be given to our IT. It all has to be pre-defined as to which members of the sponsor trial team would like access to our eTMF. We cannot give the entire trial team members access in one go; it is as individually-assigned access to them.
24/7 eTMF Access for Sponsor Some CROs provide 24/7 eTMF access for the sponsor. Wherever they may be in the world, as long as they have a laptop or a PC with an internet connection they can have real time access to their documentation with the CRO eTMF.	**Sponsor Working with many CROs = Multiple eTMF Systems** Depending on what type of systems and what type of content management they're using, CROs do have different ways to renew their technology and have different means of how to get the documentation into the eTMF system. Coming back to the first burden, also of learning to navigate new systems, obviously if you have a large

	programme and you have, say, many CROs each having a project within that programme, then you might find that the same sponsor trial team member has to learn to navigate multiple new systems depending on which CRO they use. Each CRO will have their own information technology systems that may not all be the same across the board.
Increased SOP Compliance/ICH-GCP Accreditation When utilising the CRO eTMF, the CRO staff who are involved with the eTMF have already read and acknowledged all SOPs that are relevant for working within the eTMF. Thus there is no cross-company SOP reading and acknowledgement – and maintenance obviously – that has to occur when using the sponsor system/eTMF. And also, within my CRO all persons, especially for records management, who are involved with the eTMF are all ICH GCP accredited.	**Problematic eTMF Delivery if Systems are not Agnostic** Ideally the CRO would like the sponsor systems to be agnostic with their own, however we know this is not always the case, and sometimes we do come across problems when trying to deliver the eTMF to the client. Sometimes it may come down to only having a CD-ROM with the PDFs attached. And as we know, that's not always the best way to deliver the eTMF. The best practice would be if we had full interoperability with the sponsor and the CRO, however we do realise that's not always available.
Improved Document Quality/Reduced Findings What we normally find within the CRO eTMF system is we have a centralised group of dedicated people who will review the quality of the document – not the content. The quality, in which, that we ensure we have a good image; we provide submission-ready PDFs to the sponsor within the CRO's eTMF system, in which they dedicated group are all working as one. We have a centralised group of like-minded people who are all processing the documents to get into the eTMF, ensuring that we have a consistent flow of documents – good quality documents – and that the eTMF documentation thus makes sense which, inevitably, should reduce findings on the eTMF.	**Mapping non-TMF Ref Model Filing Structures** When we have a CRO or a sponsor who do not use the trial master file reference model, of which we're on version 2 at the moment – we are currently moving onto Version 3 – it can be very difficult in order to know where the sponsor would file their documentation versus where the CRO would file their documentation. And if we have a fully agnostic system - the systems can interoperate - then we would like to move the documentation through from system to system. However, if we have a mismatch in filing structures it can prove very difficult. However, if both the CRO and the sponsor are both using the TMF Reference Model, then that's not so much of a burden but it does become one when they're not.

An Unparalleled Industry Platform Building Best Practices to Advance Your TMF and Guarantee Compliance

7 - 9 September, 2015 - Hotel Alimara Barcelona , Barcelona, Spain

For more information go to: www.tmfeurope.com
Email: enquire@iqpc.co.uk
or Phone: +44 (0)207 036 1300