10 KEY INSIGHTS ON CLINICAL PARTNERING

CLINICAL OUTSOURCING & PARTNERING WORLD Europe 2015

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This is the year….

We can increase the efficiencies of clinical trials through collaboration, innovation and enhancing quality. It is time to take stock on previous partnerships, current projects and future alliances. Where are the opportunities? How can we work differently with our partners? How can we embrace the changing technologies? How can we sustain effective clinical partnerships? These are crucial questions and ones that we answer in the coming pages. Our speakers, pioneers in clinical partnering and outsourcing, give their invaluable views. Hear from wide range of organisations as we tackle industry challenges head-on.

This year's event, the 8th Clinical Outsourcing and Partnering World Europe 2015 will examine the latest developments in outsourcing and partnering, exclusive case studies on new partnering initiatives, and new technologies. Join us to transform your clinical partnering strategies and create much more efficient clinical trials.

Gaby Anthonijs
Global Vendor Quality and Compliance Oversight
Janssen Pharmaceutical Companies of Johnson & Johnson

What do you see as the biggest trends in clinical research?

- Continuous mergers, acquisitions and joint ventures
- Open-sourcing life science on how to apply the lessons learned from the open source movement in information technology to life sciences discovery and development, which hold the promise of accelerating the R&D process
- Research-by-consortium is becoming an important part of the R&D pipeline, the "science of collaboration."
- Putting patients at the center of things - medical innovation, healthcare decisions, outcomes research etc. The FDA has launched a new Patient-Focused Drug Development Initiative. The FDA has conducted five of the twenty planned disease-specific consultations on benefit-risk and has issued a series of reports summarizing patient community input for sponsors and innovators to learn from

Which factors make for a successful and sustainable clinical partnership?

Sustainable, mature clinical partnerships depend on implementing processes for conducting trials agreed upon by both Sponsor and partner(s).

Success factors maintaining transparent communications, reinforcing, recognizing, and rewarding activities.

Well managed outsourced relationships yield 4 key benefits:

Alignment: ensuring your business priorities are reflected in service performance across suppliers
Communication: rapid and effective dissemination of feedback and information to effect positive change and business alignment
Consistency: single point of contact for all facets of support across programs, vendors, technologies, and geographies
Results: monitoring, reporting, and optimizing enterprise performance data to improve the cost and quality of customer experience

Governance and operational model:

- Ensure clear communication pathways about study status, performance, metrics and key performance indicators exist between the Sponsor and partner(s).
- Select CROs with a good fit for the Sponsor, with an aligned governance model.
- Investigate CRO's outsourcing track record and partnerships, and the successes of each, to verify that these were in good standing.

What is the number one challenge in clinical partnerships and why?

- Pharmaceutical companies are increasingly turning to outsourcing activities to CROs to reduce operating costs and increase focus on core competencies.
- Besides the benefits of outsourcing, there lies a significant risk as the responsibility to ensure quality and integrity of the study in compliance with all applicable regulations, and the clinical research protocol always resides with the Sponsor (see ICH-GCP section 5.2).
- Therefore, it is of main importance that potential risks are proactively identified through verification that business partners, CROs and their employees are maintaining compliance with their processes and training, diligently monitoring for changes that might create new risks or compliance gaps, and investigating and remediating incidents in a timely manner to avoid future occurrences.
- Establish a framework for open discussion, management and resolution of issues in a timely manner by installing an appropriate trigger system that flags areas on non-compliance or substandard quality both with CROs and Sponsor to ensure proactive management of potential risk signals between CROs and Sponsor.
- Continuous work on further improvement of oversight of CROs in order to properly address these critical requirements is key.

What do you look for in a clinical partner?

- Focus on best-of-class provision of specific CRO services, therapeutic expertise, desired CRO staff capabilities to provide targeted, cost-effective use of experienced professionals to increase and decrease resources and activity without affecting internal Sponsor head count which allow Sponsors to focus on their core competencies.
- Ensure that the CROs had clear communication pathways with the Sponsor about study status, performance, metrics and key performance indicators.
- Select CROs with a good fit for the Sponsor, with an aligned governance model.
- Investigate CRO's outsourcing track record and partnerships, and the successes of each, to verify that these were in good standing.
- Ensure to develop and describe jointly the standards, expectations, roles and responsibilities of Sponsor and CRO partner(s) with respect to managing quality for the services and/or deliverables defined in each partnership.
- Early communication of serious Risks and issues is good project management whereby escalation is activated via a specific communication pathway, with a clear goal for a decision to be made and/or action to be taken.
- The intentions of these jointly-owned plans are to ensure adherence to relevant regulations and standards, e.g. International Conference on Harmonization and Good Clinical Practice guidelines where applicable, standard operating procedures (SOPs), peer-reviewed scientific standards, and written legal agreements, and to promote consistency, transparency, and open communication of quality activities among the partners in order to promote proactive and effective management of subject safety, clinical trial quality and compliance.

What are the impacts of RBM on clinical research?

- Traditional systems for managing clinical trials typically include a combination of software and paper-based processes intended for a variety of purposes, including project management and milestone tracking; safety/pharmacovigilance reporting and tracking; document management; trial master file maintenance; and electronic data capture and query management.
- Through RBM both Sponsor and CRO can focus on the availability and monitoring of real-time data and can act accordingly with a pro-active real-time approach in case any mitigation activities are required allowing a pro-active decision making process in issue management.
- Risk mitigation strategies have little value unless they are executed, monitored and analyzed continuously throughout the trial's lifecycle. Sponsors and their global project teams need a comprehensive and compliant solution, one that allows trial oversight through real-time proactive risk assessment.
- RBM also gives the opportunity to de-risk protocols and establish controls and oversight measures that can be monitored through the review of real-time data analysis.
- The availability of real-time, continuously analyzed data and configured workflows greatly reduces, or even eliminates, the potential for individual bias in issue management and decision-making.
- The key to efficiently enabling risk-based monitoring is ensuring a continuous flow of study and site data, combined with analytics, which are then monitored for trends to inform real-time decision-making. With cloud-based and real-time access to actionable risk and performance indicators through a private infrastructure available via the Internet, global project teams would have complete visibility to critical information, analytics and associated workflows, providing clinical trial sponsors with a consistent method to evaluate, manage and mitigate risk.

Yuri Martina
Vice President Clinical Operations
Shionogi Ltd

What do you see as the biggest trends in clinical research?

The use of more and more of the technologies, eg. cloud.

Which factors make for a successful and sustainable clinical partnership?

Many factors. The back bone is our understanding of the ways of working and building shared expectations and all the infrastructure and constant communication around that.

What is the no 1 challenge in clinical partnerships and why?

When you look at data from the perspective of the vendor or service provider and the pharma industry, I would definitely say the major challenge is having 'different objectives'. You have the vendor on one side and the pharma company on the other and they need to deliver a project together. Of course they *say* that they are on the same page, have the same objective, but, in reality, we know they have different objectives and that's clear because each one is a different organisation.

What do you look for in a clinical partner?

It's really project specific but in general I look for reliability and risk-sharing. So the willingness to take accountability and sharing whatever is needed. Also experience and flexibility.

What are the impacts of RBM on clinical research?

As of today, it's a great idea. It sounds great, in that I've already worked on several projects where you have large programmes with over 3,500 people and several studies within that programme. I think in the industry as a whole, there is still a lot of resistance to it, but it can have a huge impact on the way we do business, the way we interact, not only externally but also internally, and the way we design our departments.

Jo Sawyer
Head of External Partnerships
Novartis AG

What do you see as the biggest trends in clinical research?

There is an increased desire for innovation across all the traditional elements and components of trial design, conduct and reporting. The trend is demonstrated by the implementation of technology, married with a questioning of the status quo for how companies plan and execute. So instead of looking simply at a location and population way of being competitive, (ie. looking at better locations and more niche populations) we are moving to an area of better analysing the data we generate and analysing both the productivity and effectiveness.

Which factors make for a successful and sustainable clinical partnership?

Communicating in a common language, a lingua franca. When partners take time to learn each other's language you understand more. The other way is to be honest and look in the mirror and evaluate your own behaviours and drivers before you go out and talk to anyone.

What is the no 1 challenge in clinical partnerships and why?

I would say change is really the no 1. Dealing with change. The reason I say this is it comes from my own experience: creating a partnership not only takes a lot of energy and resources, it takes quite a long time. Pharma is a dynamic world and it doesn't matter whether it's big pharma or small pharma; it's complex and it changes on a regular basis. And what we say at the beginning of trying to create a partnership often changes and what you aim for is often a different place to where you land and it's not necessarily the people involved in the partnership who cause the change of the landing site. You aim in one direction, you land in another because the world around you has changed, the spinning forces, have knocked you off course. It's not necessarily the people changing their minds, it's the situation, the world environment is changing.

That's really difficult for people who are building the partnerships to accept and not get into a culture of: 'You said you wanted this but then you change your mind and you are now giving me this' or 'you promised me a five thousand billion dollars worth of work and now you're only giving me a billion dollars'. It's still pretty good!

What do you look for in a clinical partner?

For me it's complementary skills and behaviours. I don't want a clone, I don't want people to do things exactly my way. I want people who can bring something to the table which I haven't got, cant' get, or won't do. But there has to be a case of, one and one should not equal two – we should try to get to three!

What are the impacts of RBM on clinical research?

My company does a lot of RBM. I personally think right now the jury is still out about evaluating its long term effectiveness and efficiency and whether or not by moving to this RBM kind of world the onus of data responsibility and activities move from the sponsor to the site. By doing this, whilst it might make our world more efficient, and more cost effective, what is the strain being placed on the site level?

Geno Gregory
Associate Director, Strategic Development, Global Phase 1 and Early Development Strategy
Johnson & Johnson

What do you see as biggest trends in clinical research?

There is definitely a lot of outsourcing activity that's moving away from the sponsor. And definitely a huge drive to reduce cost, and some of them are moving to the de-risking concept so the EMA and the FDA are putting in place more analytical risk based monitoring and focusing more on critical quality parameters versus the traditional approach.

Which factors make for a successful and sustainable clinical partnership?

I think it's definitely open communication and the whole spirit of partnership rather than seeing the prevalence of CROs as a service; more partnering with them proactively to see that they also have equal value in the success of the programme.

What is the number one challenge in clinical partnerships and why?

I think from my perspective, and I definitely put a quality hat on here, is the whole realm of open communication and actually being able to break down some of those hurdles that are a barrier to information sharing.

What do you look for in a clinical partner?

Definitely the capability, quality and the speed at which they can deliver.

What are the impacts of Risk Based Monitoring on clinical research?

I personally think it's a good thing because, compared to the traditional model, you mitigate risk up front; you really focus on the risk parameters that matter, and actually put resources where needed. I also I think it is a good example of "plan do check act" which means you mitigate risk up front, but if you see issues you still act on it, rather than leaving it to the end in the traditional model.

Mireille Zerola
Clinical Data Management Expert
Boehringer Ingelheim

What do you see as the biggest trends in clinical research?

Looking at it from a system's point of view, I see technology advancing at quite an alarming rate and imagine it's only a matter of time before it touches all aspects of research. We will start to catch up with the likes of the banking industry and the retail industry and use more iPad technology and more real time capture of patient data; with that will come a whole degree of analysis in terms of the types of monitoring that we can do.

Which factors make for a successful and sustainable clinical partnership?

You can look at this in different ways. My area of work is risk based monitoring and implementing a different way of working with the sites and investigators. At the moment we are really spending time trying to optimise that partnership and that partnership is about education and asking investigators to understand the way that we do research these days; recognising that they are in control of their data, what happens to their patients and we are here to support that process. In the past we've really been much more of 'a holding hands' kind of partnership, now we need to empower our investigators to recognise that we are working differently so for that relationship/partnership to be successful we have to educate and we have to empower our investigators so they know the way we work will be changing and they can be part of that process.

What is the no 1 challenge in clinical partnerships and why?

The biggest challenge is to invite our partners to come with us on a journey of change. We have to evolve like any other business; we have to get leaner and we have to get more efficient but there is a huge hesitation – the whole concept of change is scary and patients lie at the heart of everything we do, so for people to think about change, it's a little bit risky: they think, if it's not broken why are we trying to fix it?

But for our patients to get the benefit of clinical research we need to become leaner and more efficient; take their clinical research and optimise their participation. So the biggest hurdle for me is inviting people to come with us on this journey of change.

What do you look for in a clinical partner?

In terms of a partner, someone who wants to collaborate; collaboration is the key; you want someone to roll up their sleeves and be willing to work *with* you; it shouldn't be a one-sided relationship; everyone has to an opportunity to contribute and to listen and come to an optimal solution for everyone.

What are the impacts of RBM on clinical research?

The implementation of risk based monitoring is an end-to-end quality approach. So for me, I'm really wanting to see smarter protocols that take the science and make it meaningful so we are performing. We need protocols fit for purpose, not big beasts.

A huge benefit for me is having really good solid and robust protocols. And at the end of the trial it will be powerful to be able to qualify the benefits of RBM. We'll be able to say we will be much more in control of the quality dimensions, because with RBM you almost have to set tolerance limits so at the end of the trial you'll be able to say where you were with those tolerance limits. The beginning and end of a trial I see as important drivers for implementing RBM although others tend to focus on the middle bit (just the impact on onsite monitoring) which is important and fair, but we shouldn't lose sight that it's much much bigger than that.

Russell Svensen
Head Clinical Operations
Ipsen Pharma

What do you see as the biggest trends?

Patient reported outcome measures.

Which factors make for a successful and sustainable clinical partnership?

Honesty, definitely. Professionalism and adaptability.

Professionalism – we have a code of conduct, the industry has certain expectations of us and we have to conduct ourselves in a way that is appropriate and right. And sometimes for one reason or another we are put into a position where it's very enticing to take a short cut, but we mustn't; even if it's not what one or more of the parties want to hear. I'm not a great believer in speed to market, (ie, of quantity, that we have to process everything and do as much as possible.) I'm a great believer in quality; I believe that quantity is a red herring and can often lead, and has led, to excessive costs in drug development. So if it ends up in crisis management, that's very expensive and swallows up the corporate resources we have. So focus on quality.

Flexibility, within the bounds of an acceptable code of conduct; and collaboration as opposed to communication. So in a project, if there's going to be a partnership, by its very term means two or more people or organisations working together, and that means collaborating; it does not mean two or more organisations merely communicating. You can over/under/miscommunicate; you can send out confusing/misleading communications; that's not collaboration. Collaboration must be positive, has a component of which is communication, but communication around enhanced, constructive collaboration.

What is the no 1 challenge in clinical partnerships and why?

There's a number of different types of partnerships. There's the partnerships between ourselves: and vendors; and collaborative sponsors; and regulatory and ethics authorities; and sites; and patients. So to be successful in that I think you have to acknowledge the interests of everyone: what is at the core of their interest, and find a common agreement.

That's a complicated answer. There are many different partners, there isn't a one size fits all; Meeting expectations without undue burden; because the patients don't want to be burdened, but they do want to take part in clinical trials; saying this to the investigators so they don't want to be unnecessarily burdened; we want to meet the expectations of the regulatory authorities with the submissions etc. but equally there's an awful lot of paperwork we have to complete in that regard, submissions, that's a burden. It's in everyone's interests to try to work together to reduce the

amount of rework and unnecessary interaction/work and streamline it all to a point where it's efficient, productive, *and* yet we still comply.

We are a very regulated industry, and that can at times be stifling and daunting and can bring about significant delays in the development of key drugs for example; and so that's a challenge – in place for a good reason – but we should look at ways we can try to improve that. The HRA realise that their system is too cumbersome and the ethics approvals systems are too complex. But even now unfortunately they haven't quite got it right. A long way to go. amount of rework and unnecessary interaction/work and streamline it all to a point where it's efficient, productive, *and* yet we still comply.

We are a very regulated industry, and that can at times be stifling and daunting and can bring about significant delays in the development of key drugs for example; and so that's a challenge – in place for a good reason – but we should look at ways we can try to improve that. The HRA realise that their system is too cumbersome and the ethics approvals systems are too complex. But even now unfortunately they haven't quite got it right. A long way to go.

What do you look for in a clinical partner?

They've got to be knowledgeable and experienced. For the most part, conducting clinical research work requires competence – informed and able individuals and organisations; not just individuals, organisations too. For example, you can have a company of highly experienced people but if the structure of the organisation and its internal communications systems are not optimal, then even those people can't function as they should do, both with internal projects and external communications they have. So looking for a partner, whether an individual or company, you want to think that they have learnt the lessons of the past, put in place quality systems and have highly experienced, motivated, and enthusiastic sales staff. Hard to judge, how do you judge that? Difficult, but reputation, face to face meetings, due diligence, are all the critical factors to put into place; not just listening to sales pitches; it's not always just about a bottom line, a number; what's the point of several million quid on a study if it's £500 less than a competitor or they can't deliver in time?

What are the impacts of RBM on clinical research?

If you're not monitoring the risks, you are at risk and it's dangerous. That's often the case in observational based studies where there is no monitoring. You get to the end of the study and have wasted money –it doesn't mean anything. Concept of RBM is good, whatever the reasons behind it. It seems to be an accountant's approach to doing clinical research.

We should be monitoring studies, attuning monitoring, but also put a component of "are these sites at high risk? Should we monitor them more frequently? We should be monitoring the number of queries that are generated on site, the type, the frequency, the resolution, the time, and adjusting our monitoring according to that. That should be done as a matter of course, not as a RBM approach, but as normal.

I don't see any risks, only benefits; the biggest danger is that we step away from more frequent monitoring and end up with arguably dirtier data down the line. It depends on how you set up your risk profile. What are you actually looking at to begin with before you bring about enhanced monitoring of any site. You could miss what's important because you aren't monitoring it at a frequency you otherwise monitor, and you are looking at certain risk components that you think you've got collected, but in fact there's a few that you have missed. It should be in line with the National Institute of Health Research (NIHR). They talk about feasibility and the ability of an investigator to recruit patients and they collect metrics; so you can look at that from a risk perspective. One is a risk of including a particular site; and up until now unless you had an isolated database inside your own company you don't know. You go with the investigator saying he can find the right number of patients but you don't know until you start the study. Then you find they can't, they have been way too optimistic. You can lower that risk by using the institute now because they are building a database on performance so if an investigator says he's going to recruit a certain number, then they are accountable for that and if they don't recruit it then, after a while that trend, that low performance becomes apparent, and that's reported back to sponsors. So we can find out if someone is in fact able to recruit the number of patients. The Institute is engaged in a risk assessment based around this ability.

What it's not engaged in is a quality assessment based around monitoring and that's probably the next stage for it. I've asked them on a few occasions if they have any plans with respect to monitoring the number of queries that sites generate because that's generally your measure, that metric appears to be a bit of a dark metric for people to gather and share. I've been involved in many many sites and not many studies will provide meaningful metrics in an ongoing fashion, cumulative or incremental on the quantity and quality of queries being generated at site level. What normally happens is the queries are raised and resolved in an *ad hoc* fashion but you rarely see anyone doing a detailed analysis on the overall performance of sites. And for risk based monitoring you are going to need that. It needs some measure to be put in place to be got around (eg staff turnover, general engagement and query resolution) and at present we don't have those tools in house but if people are willing to invest money they will see a return of higher quality.

Dave Walker
Senior Director, Clinical Development
Norgine

What do you see as the biggest trends in clinical research?

Quality: there are increased requirements to demonstrate vendor oversight and the expanding remit of GCP and evidence collection to not only do the vendor oversight, but to be seen to be doing it.

Which factors make for successful and sustainable clinical partnership?

Realistic expectations. Then once those are agreed, the delivery of promises. What doesn't work well is when everyone agrees and then one side lets the other down!

What is the no 1 challenge in clinical partnerships and why?

There are so many that come together. I think probably some of the challenges are financial. As ever, CROs role is to make the most money they can out of a partnership and the sponsor's role is to get the costs down as low as possible. I think probably the biggest challenge is an analysis of hours. You look at various roles and people say, we are going to spend so many hours here and so many hours there. The biggest challenge is understanding exactly how those hours are being used because no two groups do everything the same. You could look at a bid and see where groups do one hour there and 10 there, and you need to understand the delivery for those hours, why people do it differently, what's the best approach. And that ultimately boils down to money because in a limitless pot you'd spend 10 hours on both tasks but you can't and you're trying to work out efficiencies and get costs down but at the same time you are thinking, 'you want to make sure all your bases are covered and you aren't getting into trouble downstream'.

What do you look for in a clinical partner?

Most important is a mutual fit in the sense that the two companies understand each other's objectives to succeed; and then both come together to achieve those goals which may not be exactly the same but are hopefully going in the same direction.

What are the impacts of RBM on clinical research?

Good and bad. There are some advantages in that you focus on the risks. You think much more broadly about different sites and aspects of the study and then focus resource on where you see the greatest risk or potential risks. I think the chief advantage is that you can get that wrong (you won't be right 100% of the time and the risk is often where you least expected it) and it also goes back to the increasing role of GCP in running studies but not everybody in Quality will be enamoured by RBM. That may be controversial and I'd be interested to hear other people's views.

Olena Goloborodko
Senior Manager Global Contracts and Outsourcing Management
Astellas

What do you see as the biggest trends in clinical research?

Strategic cooperation between CRO and pharma. This has facilitated not only traditional lower cost services but also risk sharing opportunities. It's about cooperation between pharma and CRO as strategic partners and for development purposes.

The early involvement of CROs in clinical programmes means that pharma benefit from the expertise of CROs, but it requires investing in a long term relationship and leveraging the strategic partnership and attributing dedicated resources to support sponsors throughout several programmes.

Which factors make for a successful and sustainable clinical partnership?

The key factor is trust and a willingness to invest in relationships on both sides. Trust must be based on shared experiences, not only initial sharing of goals, but also adjusting to changing environments and being flexible on both sides.

What is no 1 challenge in clinical partnerships and why?

Unspoken assumptions – because quite often the interpretation of parameters are different on CRO on the sponsor side and therefore it's important to manage expectations and qualify assumptions.

What do you look for in a clinical partner?

The right approach and delivery of promises.

What are the impacts of RBM on clinical research?

It's an innovative approach, and the consequences are not clearly visible yet although a lot of ongoing comparisons show the benefit of RBM to companies in terms of better quality and financial abilities. However, I think RBM is having a beneficial effect on the pharma industry and it will be enhanced.

Robert Janiak
Director Strategic Partnership Delivery & Continuous Improvement
Merck

What would you say is the number one challenge in clinical partnerships and why?

Probably the fact that each partner has to understand the structure of each other's organisation and how this can influence the successful partnership and delivery of clinical trials. Equally important is that you need to have a dedicated team responsible for the partnership and working on partnerships from each organisation.

What do you see as the biggest trends in clinical research?

Very complex trial protocols; very complex trials; a lot of biomarkers to be used; blockbusters and more drugs that are targeting relatively small populations; partnering between companies to develop drugs due to high costs and to share risks.

Which factors make for a successful and sustainable clinical partnership?

Transparency; a dedicated team; and a shared understanding of the goals of each partner.

What do you look for in a clinical partner?

Experience, open-minded attitude and a dedicated team; and again, transparency.

What would you say are the impacts of RBM on clinical research?

I would say at the moment it's probably a little bit underestimated and still in a phase where everybody is jumping on the bandwagon even though there is still quite a lot of uncertainty, especially relating to the submission and acceptance of the data by regulators. There are also a lot of learnings.

Ian Hodgson
Associate Director, Clinical Operations
Takeda

What do you see as the biggest trends in clinical research?

I think at the moment the biggest trend is around RBM, the biggest push for the industry.
And the other push is about really making outsourcing work.

Which factors make for a successful and sustainable clinical partnership?

I think the number one factor is people. To make a clinical partnership work, I think you have to have that professional/personal relationship at the heart of the partnership and you really need to invest in those. There are always bad times in clinical development where things go wrong and unless you have a basis of trust you have nothing to draw on when the frustrations and the inevitable difficulties happen. So I think that's the key thing. I don't think you can have a corporate relationship unless you have people connecting underlying that. What makes it work is people working together and being trusting and collaborative, that's the most important thing.

What supports all partnerships is having transparency of activities; clarity about what everyone is doing and that helps people work together. If we know what each other is doing we stay out of each other's way and we also have confidence to trust others if we can see what other people are doing and how well it's working. So transparency is a really important aspect to partnerships.

I think we haven't ever as an industry been best served by technology; it surprises me that in 2014 we are struggling to have really effective IT systems to support development. Some systems are maybe starting to touch that point like Presario and Claris and so on but they are still a way away from really being effective and seamless in transparency about activities.

What's the no 1 challenge in clinical partnerships and why?

The no 1 issue is probably lack of focus on the ultimate goal which is to bring the drug to the patient. And I see from team level up to executive level people getting sucked into minutiae, and maybe politics, while what we should really be focused on is how we are we going to move that drug closer to that patient. And when you put it into that perspective it helps people come together and focus on solving issues rather than pointing fingers or dancing round the issue.

Most companies want to have this patient centric approach in their corporate goals. But what does that really mean to people? And if we have that professional focus it has a profound impact on how we work.

What do you look for in a clinical partner?

Someone that can understand the 'patient perspective', but work flexibly and efficiently. It may be my character type, but I'm not *so* interested in process. If it's not working then the process needs to be changed. But in a partner I'm looking for someone who can focus on the delivery and not necessarily how we get there in a rigid fashion although we are a highly regulated industry so that's not to ignore compliance. We need to be compliant, that's important, but I don't think we should necessarily be slaves to structure if it gets in the way of moving things through efficiently and faster; so we should always be open to innovation and new ideas.

What are the impacts of RBM on clinical research?

I think people may have raced into RBM without thinking of three aspects.

Do we really understand what the regulators want? Because I think the FDA and EMA can be fickle so you can give them what you think they want and then they tend to be quite revisionist and come back and say, no that wasn't what we were thinking. And there are some regions in the world where you can't do RBM, like Japan and China.

An area where we may be unprepared is infrastructure and our inability to deliver it. Although I think there's been a huge effort and we are much better placed this year than last.

Very few people have thought about how prepared the sites are for RBM. I feel that investigators are not well prepared and adapted to having fewer monitoring visits. As an industry we have rushed into this and it's pulled the security away from a monitor being on site regularly and, for larger companies and for outsourcing, it's further reducing any engagement we have with investigators, so we have to look at ways we can replace that or change that and I don't know that many companies are really looking at that or thinking about what they can do to have that level of contact and continuous engagement with their investigators.

Dr George Tzircotis
Licensing Manager, Centre for Drug Development
Cancer Research UK

What do you see as the biggest trends in clinical research?

Increased collaborations, both between industrial partners as well as academic-industry partnerships, to address drug development challenges in emerging fields (such as immunotherapy, precision medicine and in the use of novel treatment combination strategies).

Which factors make for a successful and sustainable clinical partnership?

Upfront alignment of the partners' goals in order to achieve a mutually beneficial objective and clear communication channels throughout the partnership.

What is the number one challenge in clinical partnerships and why?

Reaching advance agreement on the responsibilities and duties that each partner will have as part of the collaboration. Partners often have differing expectations of the requirements necessary to achieve the goals of the collaboration.

What do you look for in a clinical partner?

A partner whose strategy and expertise complements the project in order to give it the best chance of success.

Dr Tim Miller
President and CEO
Abeona Therapeutics

What do you see as the biggest trends in clinical research?

Gene therapy is a hot topic right now. In particular the viral gene therapies that have made a lot of breakthroughs in the past two to three years; so diseases that were previously thought not to be potential business products, or viable business models are now being viewed by the venture capital community as viable targets and so you are seeing a lot of rare disease gene therapies get a lot of financing and moved out of pre-clinical research and into clinical trials. So if you look in 2013-14, there are about 20 deals that have been done, multi-million dollar deals and some of which are initial public offerings in the US when companies have got a lot of financing to buy into the clinical trial for gene therapies. So there's not a day goes by when you aren't reading about another deal or another clinical trial for a gene therapy product.

Which factors make for a successful and sustainable clinical partnership?

Communication is the probably one of the bigger ones; experience as far as finding a CRO or a clinical team that has experience of working within your disease model or your pharmaceutical area; you are usually trying to get them both but often opting for one or the other.

As for CROs, I think they like to talk about what their areas of expertise are and you suddenly have a lot of boutique or niche CROs that focus for example on CNS disorders and all therapies and drugs around that.

So what makes a good partnership? Open communication based on experience and financial appropriateness for both the sponsor and the CRO that handle the trial together.

What's the no 1 challenge in clinical partnerships and why?

I exist in the early to mid-stage biotech stage where therapies are moving out of academic institutions, universities, hospitals, and into the small trials, the middle stage trial. And much like licensing agreements, the interaction between CRO and sponsor is really important.

You can try to make sure you can do an a la carte selection with your CRO to gYou et exactly what you need for a price you can afford that can then be scaled up to your next stage of trial. So having a CRO that's flexible and being able to do any of the 25 specialities they might focus on is important to identify in the beginning. One of the things I do when I'm interviewing CROs, I want to know how we can mix and match, for example I may want to do data management or study monitoring, or pull out another piece like patient travel. How can my partner adapt to my needs?

What do you look for in a clinical partner?

Expertise is the focus point in the disease area. It doesn't make sense to have study monitors and safety monitors that don't have experience in your disease area because when they are trying to assess safety events, they need to be able to appropriately understand what is a safety issue or what's relevant. Open and constant communication is important. And really so too is adherence to timelines and making sure the CRO isn't going to charge you for every out of scope occurrence.

Clearly there's an understanding that if there's a big variation in the plan you revise the contract; but small things that are part of the natural development of a clinical trial, shouldn't be a 'hidden catch' item; I've seen it happen where an inexperienced biotech company would come in and a more savvy CRO would come in and manipulate a contract knowing that it was going to be a whole lot out of spec. So you need flexible people you can trust. And a good CRO relationship is one you can carry through phase 1, 2, 3 trials. Personal relationships are also important up to a point: you start working with two or three CROs, you develop relationships with the study manager, the project manager and the development team so if they move, sometimes you go with them and give them your business.

Want to learn more?

These key players will be speaking at the Clinical Outsourcing & Partnering World Europe event, happening next 10-11 March in London.

Tackle the key challenges faced before, during and after outsourcing in clinical trials.

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