Discovering the Value of a True Partnership between American Sponsors & European CROs to Develop a Successful Working Relationship while Conducting Clinical Trials in Europe

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Outsourcing in Clinical Trials Europe
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Intent of Outsourcing

- Improve efficiency (high quality deliverables)
- Cost (acceptable price)

- Impact of increasing clinical costs & need for more data FASTER, means small companies are faced with the challenge of how to do more with a smaller budget
How do we go about it?

- Look at your internal resources & determine what expertise you have vs what expertise you need
  - If you are conducting a trial in Europe, do you want a CRO from America to manage your sites in Europe?
  - Do you need the expertise that a European CRO can offer?
- Which outsourcing model is the best fit
- What kind of relationship do you want with your CRO and why is that so important?
Outsourcing Models

Which ‘Outsourcing Model’ is most suitable for your company?

- Full-service model (all-inclusive CRO)
- Functional model (specific vendor for each service need and function)
- Hybrid model (company control with access to SOPs & expertise of full-service CRO)
- Risk-sharing model (strategic partnerships with shared risk and shared reward)
Involve CRO from the Beginning

- If possible, actively engage the CRO in the study design process
- **Teamwork** is critical in building a collaborative relationship
  - Create a team Contact List
  - Set up recurring teleconferences
  - Make the CRO an extension of your internal team
  - Face-to-face meetings
Challenges & Rewards: American Sponsor working with European CRO

Challenges
- Time zone differences
- Language & cultural differences
- Regulatory and Ethics requirements are often different

Rewards
- Educational opportunity
- Open to creative thinking
- Collaborative ‘global’ outlook
Effective Global Trial Management

- Communication is key
  - Consistency, clarity, form & timing
  - Remember the power of Listening
  - Don’t wait till a problem occurs to escalate communication…ongoing from the beginning
- Create structure with flexibility
- Set mutual expectations and areas of responsibility but be willing to shift them as needed during the course of the trial
- Develop a rapport…don’t forget the power of laughter in developing a relationship
Communication is Key

Buck, you get along with everyone. What's your secret?

Nobody hates a listener!

Buck Stopper
Old Pro
Outsourcing vs. Dictating

- Collaboration is a skill set and a dictatorship is not a collaboration
- A good leader is not a dictator
- Maintaining total power and control leaves little room for learning & progress
- Create an environment that is open to suggestions
- CRO & Sponsor must find synergy, especially with an America Sponsor & a European CRO
Dispelling the Myth ‘Bigger is Better’

- Small biotech and large CRO means:
  - Goals and priorities can be misaligned
  - Team turnover can be disruptive
- Small biotech & small CRO partnership:
  - Equally invested...same goals at stake
  - Allows for relationship building which maximizes value of partnership
- It can mean the difference between success and failure
In Summary

- If CROs can continue to deliver dependable, quality service at a competitive cost, small pharma & biotechs can expect to see increased reliance on outsourcing models to support global clinical development.
- If we nurture and value the relationships with our CROs and vendors, we can maximize the benefits of the services they provide.
- Remember the goal...true synergy increases effectiveness and equals success!
Thank You