

cencora PharmaLex

Presents

CRO VS SPONSOR BEST OF FRIENDS OR WORST OF ENEMIES



The 12 Rounds for Success

Round One: Remember, you are both working towards the same goal. A successful trial with the best outcome for the patient.

Round Two: Understand who is responsible for what, set clear expectations. RACI and Milestones set early are the first steps. If they are not agreed, assumptions should not be made.

Round Three: Define what rulebook you will be following early. Agreeing on SOPs, Processes and Systems are a must.

Round Four: Training should be clear and to the point, and should be suitable for the role they will be performing. Efficient and Effective training is key.

Round Five: Explain what good looks like and measure accordingly. KPIs should be shared with all parties and performance against those should be fed back.

Round Six: No one likes surprises, so have open dialogue throughout. Communication is key.

Round Seven: Oversight is the Sponsor's responsibility, you need to ask for what you need, you can outsource a lot, but not that.

Round Eight: When using multiple CROs and Vendors, be respectful of privacy, but remember, it is your study and your data.

Round Nine: Change is inevitable. Studies can last a long time, be prepared to adapt.

Round Ten: When changes do need to be made, make sure they are communicated early to understand the impact.

Round Eleven: If end of study transfers are required, plan accordingly; how will data be provided? where will it be sent? what processes will be used to qualify it?

Round Twelve: Respect each other. You both have priorities, you both have deadlines, you both have other work going on, but together you can see this through to the end.

