Clinical Trials and Skydiving???

- Pineapple and Ham
- Tony Bennett and Lady Gaga
- Caramel and Salt
Clinical Trials and Skydiving – How are they alike?

- Risky
- Expensive
- Planning
- Training
- Working with others / working as a team
- Making sure you have the right “equipment”
- Follow through / landing safely
- Contingency plans
CRO/Sponsor Collaboration: How Working Together Effectively on a Clinical Trial is Like Doing a Successful Skydive

- Load Organizing / Planning the Dive: Establishing goals
- Assigning Positions: Knowing your team
- Dirt Diving: Preparing for success
- Assigning responsibilities: The effective use of a Gantt Chart
- The Jump: Being accountable
- Malfunctions: Expecting the unexpected
- Deploying and Landing your Parachute: Knowing the end result
Load Organizing or “Planning the Dive”
Load Organizing or Planning the Dive

- Establishing Goals
- Review the contract and assumptions (both CRO and Sponsor Project Managers should read/review/understand)
- Conduct the Kick Off (KO) Meeting immediately after the Letter of Intent (LOI) or contract is signed
- Review the scope of work during the KO Meeting
- Discuss the communication plan
Scenarios of Information and Mis-Information

- Therapeutic Training
- Agendas and Meeting Minutes
- Plans – Initial, revisions, reviews
- Sponsor expertise & input into CRFs
- CDISC vs non-CDISC programming
Assigning Positions
Assigning Positions

- At the Kick Off meeting
- Introduce / get to know your team
- Include all vendors
- Roles and responsibilities / “who does what”
“Dirt Diving”
• Preparing for Success
• Setting up expectations that are mutually agreed upon by both parties (vetting timelines)
• Assigning responsibilities
  ○ Knowing who will be responsible for what
  ○ Ensuring adequate resources
  ○ The effective use of a Gantt Chart
• Beware of Predecessors
The Gantt Chart and Predecessors

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<tr>
<th>Task Name</th>
<th>Duration</th>
<th>Start</th>
<th>Finish</th>
<th>Predecessor</th>
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Going to Altitude

Gear Check

Visualize the Jump

- Revisit the timelines often
- Reconfirm the deliverable – what it is and when it is due
- Remind the team(s) of what is expected – can be reiterated during meetings and documented in meeting minutes
Ready, Set, Jump

- Know your role / position
- Know what is expected of you and when
- Being accountable
- Follow through
The Jump
Malfunctions
Malfunctions or “Planning for the Unexpected”

- Delayed approvals / enrollment
- Revisions to output / plans
- Turnover
- Responding to “out of scope” requests
Planning for the Unexpected

- Risk / Mitigation Plan
  OR
- What to do when things go wrong
- Do you cut away your malfunctioning parachute or do you work with what you have?
Deploying & Landing your Parachute
Deploying & Landing Your Parachute

- Being transparent
- Discussing the issue with the resolution(s)
- Being open to alternative ideas
- Collaborative solutions
Focus on the End Result

- Patient safety
- Data validity
- Quality work
Know your end result before you start

Implementation

Execution
Barbara J. Ruby, Associate Project Director
(Skydiver since 1999 – D-License 24057)

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