Restarting Studies Post-COVID: For Sites, By Sites

Brian Craig, CEO, Pillar Research, LLC.: 
Managing sponsor expectations/enrollment (adjusting timelines, getting up to speed) 
Requesting the appropriate support from a contract/budget perspective.

Kate Templeton, MS, Clinical Operations Manager, Segal Trials:  
Risk/Mitigation policies (managing flow of visits, PPE, sanitation, etc)  
Ensuring employee wellbeing.

Elan Cohen, Ph.D, Principal Investigator, Hassman Research Institute:  
Bringing furloughed employees back for adjusted hours congruent to visit activity; overall staffing review.  
Utilizing remote/virtual options when available or appropriate.

Stay Safe and Stay Well.

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POST COVID Sites: Focused on Efficiency and Productivity
• Leaner and more efficient (less admin and support staff)
• Leverage technology (e-source, e-reg)
• Social media/marketing savvy
• Be sensitive to unwieldy study designs:
  • budget conscious, profit focused, cash flow sensitive
  • Be sensitive to uncertainty - cautious about investing in new staff
  • Consider fewer studies with higher enrollment per study with Sponsors that stay open
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Principles of Study Design under COVID:
- Beware there is pent up demand for studies and sites
- Focus on your primary outcome measure
- Decrease time in the office for visits (but frequent visits are important for retention)
- Compress the study as much as possible - is this the shortest feasible study design?
- Simplify studies when possible - Should X really be a deviation or can we leave it flexible? Increased deviations, decreased efficiency
- Reduce vendors & reduce vendor/site interactions - do I really need this service?
- If COVID testing will be integrated into the trial allow it to be done via prescreening process remotely - Don't inadvertently force you site to close
- If training required, train in advance of study opening
- Consider 2 stage enrollment:
  - 1st stage - sites that remained open and can enroll;
  - 2nd stage - sites that closed can open in 2nd wave once conditions clear

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Budget Principles:
- Allow for increased costs of remote monitoring - scanning/rescanning, increased staff time (video conferencing), drug accountability, etc.
- Increased advertising to sites - social media, TV, radio - traditional face to face methods are more difficult now
- Request an additional per subject recruitment fee
- Build line items for e-reg, e-source, PPE
- Request increased admin fees to allow support for site ongoing monitoring of county, state, and federal COVID regulations
- Request ability to pay some subjects in full up front

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Kate Templeton, MS, Clinical Operations Manager, Segal Trials:

Risk/Mitigation policies (managing flow of visits, PPE, sanitation, etc.).

Ensuring employee wellbeing.
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Risk Mitigation:

- Entrance Policies (Volunteers and Clients)
  - Screening Questionnaire
  - Temperature Checks
- PPE
  - For entrance, while onsite and for all work procedures
  - Procurement/Regular Inventory
- Distancing
  - Transportation, Office space, Common Areas
  - Partitions
- Reduce traffic: Virtual prescreens, staggered appointments

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Risk Mitigation:
• Sanitation Policies
  • Establish a schedule in addition to after each contact
  • Identify Staff
• Remove unnecessary items
• Hand Washing/Sanitizer
• Signage throughout facility
• Crisis Management Team
  • Compliance and Adherence Checks

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Employee Wellbeing
• Remote vs. Onsite
• Flexibility
• Find ways to stay connected
• Virtual Meetings
• Provide local resources
• Employee Assistance Programs
• Prioritize their Safety
• Clear policies, compliance checks/accountability, communication and feedback
• Make time for fun (activities, outreach, collaboration)

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Elan Cohen, Ph.D, Principal Investigator
Hassman Research Institute:

- Bringing furloughed employees back for adjusted hours congruent to visit activity; overall staffing review.
- Utilizing remote/virtual options when available or appropriate.
- Concerns patients and study participants have expressed being in a study related to COVID19.
- How is the site managing CRA visits and monitoring.

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Thank you!

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