RESCUE CONSIDERATIONS

ACM GLOBAL LABORATORIES

Course Correct with a Comprehensive Approach to Your Rescue Study

At ACM, we understand that trials often exceed limits of time, cost and/or quality. Trial rescue, particularly in its early stages, can efficiently identify and correct issues that could impact the long-term potential of the study, addressing underlying issues before they escalate.

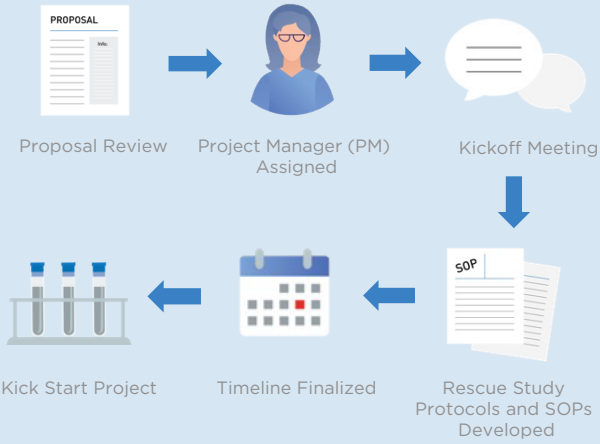
Our Process

- Every study is unique; therefore every rescue requires a custom solution
- Customized planning focused on the quality and expertise your study demands
- Comprehensive rescue services for any aspect of your clinical trial - no matter the stage*

Rescue Considerations

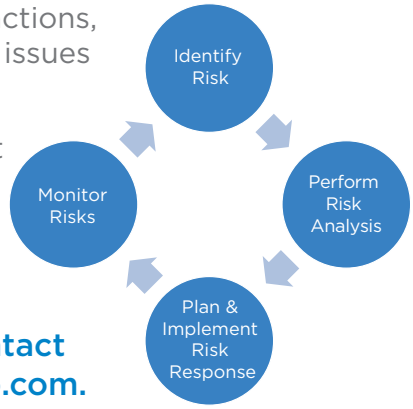
- Site Communications
  - » Kit components – review kit contents for specialty supplies/long-lead time items
  - » Site training to ensure sites are using correct kits/processes
  - » Hotline for sites
  - » Memo included in initiation kits on what to do with the old kits
- Data management – use current lab Data Management Agreement specifications so ACM can set up exactly the same
- Documentation: Final protocol, previous lab specs including lab manual, reference range document – will ensure ACM follows same specifications
- Instrument/methodology considerations
- Timelines – typically 8-14 weeks setup dependent on study complexity
- ROW – timeline consideration for import/export changes

Example Transition Plan



Communication Support

- Communication Plan
- Activity Log
  - » Key Study Documents to the ACM/ Client relationship
  - » Study Activity – actions, decisions, quality issues
  - » Site Performance
  - » Risk Management



For assistance, contact us at acmgloballab.com.

In addition to rescue services, ACM offers expedited services. We've recently introduced new efficiencies in our expedite process, designed specifically to help you accelerate your timelines without compromising quality or compliance. This means we can reduce the kits on site timeline by two weeks, based on study complexity*

**ACM can assist even if you are experiencing issues in your current study with: Compliance, Quality concerns, Resource requirements, or Missed timelines.*

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**Study must be signed by 31 December 2024; based on operational capacity of laboratories*