ADAMAS

ADAMAS CONSULTING

QUALITY INVESTIGATOR SITE ASSESSMENT (QISA)

QUALITY INVESTIGATOR SITE ASSESSMENT

The COVID-19 pandemic and its effects on individuals, the health system, economy and nations has not been seen before. The repercussions on travel restrictions, access to hospitals and surgeries for monitoring and audit purposes are far reaching, and meeting Sponsor obligations towards clinical trial subjects and employees, represents a further challenge.

The potential risk of this global COVID-19 pandemic and the associated travel, access and resource restrictions include but are not limited to:

- **AN INCREASE IN THE NUMBER OF PROTOCOL DEVIATIONS**
- **RISE IN GOOD CLINICAL PRACTICE NON-COMPLIANCE**
- **INSUFFICIENT EVIDENCE OF SPONSOR AND INVESTIGATOR OVERSIGHT**
- **INVESTIGATIONAL MEDICINAL PRODUCT (IMP) SUPPLY, COMPLIANCE AND**
- **MANAGEMENT ISSUES**
- **INSUFFICIENT MANAGEMENT AND DOCUMENTATION OF SITE-SPECIFIC RISKS**

ADAMAS'S QUEST

ADAMAS's goal is not only to provide quality assurance services by conducting high quality audits on behalf of Sponsor companies but also to add value and provide innovative solutions to ensure compliance with regulatory obligations for quality assurance and oversight, thereby ensuring that patient safety, data integrity and scientific validity are consistently maintained.

ADAMAS has developed an alternative to the traditional Investigator Site Audit (ISA) to enable Sponsors to continue to monitor compliance in these exceptional times. We refer to remote site audits as Quality Investigator Site Assessments (QISA) as some aspects of routine ISAs cannot be performed but, they do allow the highest possible degree of Sponsor Oversight and reassurance.

CAPABILITIES OF QISAS

QISAs allow the evaluation of several key aspects of the traditional ISA:

- **KEY QUALITY STANDARDS OF SITES**
- **SITE MANAGEMENT AND MONITORING ACTIVITIES**
- **ESSENTIAL DOCUMENTS**
- **ETHICS AND REGULATORY COMPLIANCE**
- **SPONSOR AND PRINCIPAL INVESTIGATOR OVERSIGHT**
- **SUBJECT COMPLIANCE AND SAFETY BASED ON AVAILABLE ELECTRONIC DATA**

Advancements in available technology, the use of electronic Trial Master Files (eTMFs), document share options, and video conferencing provide the ideal platforms/tools for QISAs.

ADVANTAGES OF QISAS

- **REGULATORY COMPLIANCE**
  - QISAs contribute to the risk-based approach in site selection for ISAs, the outcome providing Sponsors with relevant insight in identifying investigational sites requiring a more detailed, on-site ISA focussing on key areas of concern identified during the QISA
  - Demonstrates continued Sponsor oversight to regulatory authorities

- **EXTENDED QUALITY ASSESSMENT**
  - QISAs can focus on individual or a series of investigator sites, for a specific programme simultaneously or consecutively, to facilitate the efficient identification of any systemic issues
  - ADAMAS Insights© database can provide analysis on any high-risk findings to be used in determining whether the site should have an on-site audit, or provide an analysis on the whole programme to identify study-wide areas for improvement
  - A review of outsourced activities can be included in the remote assessment, e.g. Project Management, Monitoring and Site Management on a Program Level, and Document Management
  - Sponsor representatives may attend interviews and/or the opening and closing meeting, receiving first-hand and up to date information on the QISA's progress

- **COST EFFICIENCY**
  - QISAs are more cost effective as travel and other associated expenses do not apply

- **FLEXIBILITY**
  - Activities can be organised to accommodate all participants, minimise the disruption at investigator sites, and reduce the risk of time wastage (for example, waiting on interviewees, having to change audit location due to room availability etc)
  - The Clinical Research Associate (CRA) can participate remotely, thus avoiding the cost of additional monitoring visits to site
  - Anonymised data available on external databases, e.g. laboratory results, electronic Patient Reported Outcomes (ePRO), Central Reader vendors for images and electrocardiograms can be reviewed independently of the sites' availability

- **COMMUNICATION**
  - The CRA or another member of the Clinical Operations team can assist with translations during interviews as they would during traditional ISAs
  - Video conferencing systems are used to allow visual contact
  - ADAMAS has an encrypted file sharing tool, Tresorit, which enables secure access to documents

PREREQUISITES

- **ACCESS TO AVAILABLE SYSTEMS FOR REMOTE DOCUMENT REVIEW, INCLUDING BUT NOT LIMITED TO:**
  - eTMF or access to a document share platform
  - Electronic Case Report Forms (eCRFs)
  - Electronic Patient Reported Outcomes (ePRO)
  - Central reader vendor database and/or reporting systems

- **A SITE QUESTIONNAIRE MAY BE USED TO GATHER INFORMATION ABOUT THE SITE IN ADVANCE OF THE INTERVIEW SESSIONS, TO ALLOW SITE PERSONNEL TO PREPARE ANSWERS THAT MIGHT NOT BE IMMEDIATELY AVAILABLE AND HELP TO FOCUS INTERVIEW QUESTIONS AS WELL AS DOCUMENT REVIEW. TOPICS OF THE QUESTIONNAIRE MIGHT INCLUDE BUT ARE NOT LIMITED TO:**
  - Facility and equipment used
  - Known issues
  - Source data generation including 21 CFR Part 11 compliance if Electronic Medical record systems are used

PLEASE GET IN TOUCH TODAY TO LEARN MORE ABOUT HOW ADAMAS CAN ASSIST YOU DURING THIS UNPRECEDENTED TIME.

PLEASE CALL US ON **+44 (0)1344 751 210** IN EUROPE, **+1-919-341-3361** IN THE US, OR VISIT OUR WEBSITE AT **WWW.ADAMASCONSULTING.COM**.

CONDUCT AND REPORTING

- **THE QISA WILL BE CONDUCTED ACCORDING TO THE SCOPE AND WITHIN THE TIMELINES AGREED WITH THE SPONSOR. TOPICS INCLUDE:**
  - Principal Investigator (PI) Oversight
  - Protocol Compliance
  - Informed Consent process
  - Essential Documents
  - Contracts and Agreements
  - Ethics/Regulatory
  - Document Management/Filing/Archiving
  - Personnel and Training
  - Monitoring and Site Management
  - Safety Reporting review/process
  - Source Data Verification
  - Investigational Medicinal Product (IMP)/Investigational Medical Device
  - Laboratory Sample Management
  - Equipment (depending on access to documentation)
  - E-system access/security (as applicable)

- **A COMPREHENSIVE QISA REPORT WILL BE PROVIDED WITHIN THE AGREED TIMELINES**

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