

Ensuring COVID-19 Response Preparedness

Partnering with Quality and Compliance Consulting

We are living in an unprecedented global situation, and all organizations are assessing the impact of COVID-19 on clinical trials and trial participants.

Extraordinary measures may need to be implemented and trials adjusted to adapt if or when patients are unable to get to sites, sites cannot reach patients and site resources are stretched to the limit. The industry has to keep these concerns in mind to provide solutions, determine what support is necessary to keep our trials on track and how we can best provide it.

The focus should be firmly on patient safety, drug continuity, patient engagement and taking the burden off the healthcare system. Patient safety and data integrity come first; these real-time solutions can help you mitigate the effects of COVID-19 on trials we are conducting or trials conducted by others.

The Syneos Health® Quality and Compliance Consulting (QCC) team is here to support the industry in ensuring that, during this global public health crisis, the integrity of trials is maintained and appropriate actions are being implemented to assure the rights, safety and well-being of trial participants and trial staff.

Comprised of quality assurance experts with an average of 20 years or more of experience, the QCC team is able to support customers by providing deep subject matter expertise in quality with the shared goal of ensuring patient safety and data integrity and increasing inspection preparedness.

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How can we help?



Determine the full scope of the COVID-19 impact

Every study has been affected by COVID-19, but not necessarily to the same extent or as severely as once feared. The QCC team can support customers on this analysis, to quickly understand the situation for each study and at each site or party involved in the study management. The following should be included as part of this analysis:

- Benefit-risk assessment of the COVID-19 impact on continuation of the study, enrollment of new sites, start of new trials or ongoing recruitment. Risk assessment should be conducted for the trial and per site/party
- Evaluation to determine whether actions taken were based on benefit-risk considerations and follow regulatory requirements
- Evaluation of the impact on enrolled trial participants and new participants
- Changes that are well-balanced and proportionate, particularly taking into account legitimate interest of trial sites in avoiding further burden in terms of time and staffing during the COVID-19 pandemic
- Evaluation of sponsors/Contract Research Organization (CRO) changes in the oversight activities, including remote monitoring, centralized review of data and remote source data verification



Study management support

Based on this analysis, the QCC team can assist customers on the following:

- Advising study teams to implement changes that align to current regulatory guidelines and ethical considerations
- Monitoring alternative arrangements that are fully documented with well-reasoned rationale
- Maintaining risk assessment during the pandemic and post-emergency as a long-standing way of continuing the clinical trial
- Confirming that:
 - ✓ Safety reporting complies with legal requirements
 - ✓ Trial participants are informed in a timely manner by the investigator about relevant changes in the conduct of the clinical trial
 - ✓ Evaluation of changes occurs in investigational medicinal product distribution and associated correspondence with regulatory bodies
- Reinforcing oversight of activities to ensure that the sponsor's responsibilities always comply with regulatory requirements and industry standards



Evaluation of COVID-19 measures

The QCC team brings a select group of auditors, who have extensive experience with global pharmaceutical sponsors, to verify effectiveness of the strategy implemented on clinical trials execution by:

Virtual/on-site GxP audits

(e.g., investigator site, systems, internal processes, document, safety audits, vendors, CMO)

Inspections readiness

(e.g., mock inspections)

Based on results of the assessment, the QCC team can assist with:

- ✓ **SOP/procedures review and updates**
- ✓ **Contributing to risk assessment (e.g., audit outcomes, CAPA management and follow up)**
- ✓ **Continuous QA advice on SDV alignment to local regulatory challenges**
- ✓ **Reviewing study plans to detect potential gaps according to implemented changes**
- ✓ **Training on implementation of measures**
- ✓ **Contributing to risk evaluation (e.g., audit outcomes, CAPA management and follow-up)**
- ✓ **Contributing to define strategy for the SDV, respecting local regulatory challenges**
- ✓ **Training of study personnel on implementation of measures**

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About Syneos Health

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