



COVID-19 ClinEdge and BTC Networks Service Statement: Sites

3/26/2020

Dear Collaborator & Partner,

Given the increased attention regarding coronavirus (COVID-19), we at ClinEdge & BTC want to assure you that we are actively evaluating all business-related risks posed by this evolving public health situation. We are operating within the guidelines of the Centers for Disease Control and Prevention (CDC), along with other health authorities. With their guidance we will monitor this dynamic situation as it continues to unfold.

On behalf of ClinEdge & BTC we wanted to send out a list of measures that our team along with working with dozens of sites through various issues right now have identified and what has transpired with the new FDA guidance that has been distributed on March 18th, 2020. We are not stating that you must implement any of these or that we are right or wrong, but we felt this helps in supporting your ability to execute on any ongoing studies. Any stakeholder feedback that comes direct from the Sponsor/CRO will supersede our recommendations.

This information is subject to change as we monitor multiple sources of information and rely on our client partners to recommend new measures be taken. Some highlights of the measures taken include:

Establishment of a Crisis Management Team:

- Established a Crisis Management Team (CMT) and a Business Continuity Plan and Checklist.
- Established responsibilities within the team based on impact on our projects and our business.
- Implemented an individual study related risk assessment and test continuity plan.
 - Worked with a number of our clients on development of their Coronavirus Containment Policies.
- Ensure the team meets daily or bi-daily.
- Ensure the team sends a daily/bi-daily update to all staff outlining issues and challenges that have arisen that day, providing direction on any actions to be taken including risk mitigation strategies and sharing of best practices.

Operational Guidelines:

- Our physical office locations due to the gatherings of 25 or more people likely have all closed and all teams and people are working remote. All technology and compliance related processes have been built for our business to run 100% virtually and are tested throughout the year following our compliance processes.
- When the teams are able to return to the office, ClinEdge has a list of individuals at risk that will have individual customized plans that may have further restrictions.
- All ClinEdge staff will be directed to stay home when showing any symptoms of COVID-19.
- Travel for our staff is mostly restricted with some modifications based on local business needs.
- Teams are working with sponsor and site clients to implement Remote Monitoring Visits within the operation.

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- ClinEdge is leveraging virtual platforms for internal and external collaboration needs for all stakeholders on all projects.
- ClinEdge has committed to sending ongoing notifications to our clients on project-related updates as it relates to COVID-19.
- We are updating our staff daily on our preparedness steps and directives.

Patient Tools (Our team can help with templates, content or sending as you need):

- Create a pre-screening questionnaire/script that can be adopted to studies (will need to be IRB approved by your site)
- Text message, email and newsletters communication to database
- Create a patient assessment that includes assessment of coronavirus

Ongoing Communication

ClinEdge will provide you with regular updates, including ensuring our critical partners also continue to respond to COVID-19 regarding their established business practices and any changes related to the impact COVID-19 may have on ClinEdge's delivery of service.

Best,

Christian Burns | President