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Clinical Trial Conduct Post COVID-19: How to Handle the New Reality?

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Learning Objectives

- At the end of these 30’ you should be able to:
  - Describe best practices in trial conduct post COVID-19 pandemic, ensuring subject safety and well-being, qualitative data and regulatory compliance
  - List the key changes between GCP E6 R2 and GCP E6 R3
  - Describe how GCP E6 R3 is supporting a new research framework that ensures better protection against disrupters like e.g. a virus pandemic

Q&A 1

Question 1

- COVID-19 regulatory guidance per region/country: https://www.triumclinicalconsulting.com/library/
- Are these alternative ways of working to stay or will we go ‘back to before’?

Answer 1

- NO, these regulatory changes are only applicable during the COVID-19 pandemic. Afterwards we *GO* 'back to normal'.

However…

- What innovations however should outlast COVID-19?
  - Increased real-time data access
  - Remote access to Electronic Medical Record (EMR)
  - Telehealth/virtual solutions

Is change ahead? Let's see… but first question 2…

Q&A 2

Question 2

- What are acceptable and feasible ways for the conduct of remote monitoring/auditing today?

Answer 2

- For remote monitoring/auditing the following needs to be considered:
  - Conduct risk-based monitoring/auditing
    - Use sample checking as much as possible, where risks allow
    - Focus on safety and efficacy data
  - Check local regulatory/IEC/site board requirements for remote strategies to be allowed, as applicable
    - If not allowed, it stops here!
    - Only a few EU countries allow for remote SDV – check the TRIUM library for the latest updates: https://www.triumclinicalconsulting.com/library/
    - If remote SDV is not allowed, other monitoring tasks can still be done remotely if allowed by local regs and IEC

Today there is no acceptable alternative for onsite SDV if remote SDV is not allowed

Answer 2

- For remote monitoring/auditing the following needs to be considered:
  - Avoid as much as possible additional burden for the site/sponsor
  - Update the protocol or referred plans like the monitoring or audit plan with the added alternative remote strategies, as applicable (document!)
    - An overarching NTF can work as well – keep it simple!
  - Assess if contract updates are needed
  - Assess if additional consent from the data subject is needed for sharing their personal data & sensitive data (special categories of personal data like healthcare related data) using online tools
    - Always needed in case consent is the legal basis and not described in the original consent
    - If other legal basis like legal requirement or legitimate interest, the data subject needs to be informed and has the right to object
    - If needed, but not possible to collect, or subject objects or withdraws their GCP consent it stops here!

Answer 2

- For remote monitoring/auditing the following needs to be considered:
  - Recordings of any kind (audio/video/screen shots/screen printing/pictures) are not allowed.
    - Required (per the purpose) processing of data in real time only is acceptable!
    - Establish a separate confidentiality agreement to capture the prohibition if need be
  - Receive upfront and documented approval from the site, sponsor and other relevant stakeholders on the proposed remote strategies to ensure buy-in and compliance

Answer 2

- If remote monitoring/auditing is allowed, ensure:
  - Conduct as much remote review through validated systems like eCRF, CTMS, eTMF
  - The other systems are GDPR proof, meaning protecting personal data by design & default against unauthorized access, copying, recording, data breaches & leaks – test this upfront
    - Direct access to 'Electronic Medical Records' (EMR) (unique passwords required; audit trail)
    - Telecon or video (TEAMS, WebEx, ZOOM, phone, etc.) – have a script ready
    - Scanning, e-mailing, faxing
    - eSource solutions – real-time entry in tablets e.g.
  - How?
    - ISO 27001 compliance of systems used is a must!
    - Have IT provide you with documented evidence of compliance and protection
      - Example: Microsoft 365 certificates to show compliance (SharePoint, TEAMS)

Answer 2

- If remote monitoring/auditing is allowed, ensure:
  - Pseudomized or encrypted data are available and information is erased, deleted or anonymized immediately after use – also in the back-up cloud systems, as applicable
    - Non-encrypted could be needed in case of remote SDV/audit/ICF review – extra vigilance is needed here!
  - Only to invite 'must have' staff for the purpose, that already have consent for access to the personal data & repeat no recording of any kind is allowed
  - IT:
    - Have them check during or afterwards if any records were made (through data review in the background)
    - Have a representative at hand in case of issues during any remote live sessions
  - Competence
    - Preparation, Attitude & Training!

Q&A 3

Question 3

- Is the upcoming GCP E6 R3 standard supporting use of technology and alternative trial designs to weapon us against another disrupter like COVID-19?

Answer 3

- YES! And much more…

Answer 3

- Today's concerns with GCP E6 R2:
  - No focus on issues most critical for trial quality (key principles and objectives)
  - One size fits all approach not working for different trial types
  - Not considering new trial designs, emerging technological innovations, different data sources, testing facilities and service providers or other emerging complexities of the current trial climate – like COVID-19….
  - Sections 'Investigator' and 'Sponsor – 5.18 Monitoring' outdated
  - 'Checklist' and 'audit policing' perceptions

Answer 3

- GCP E6 R2 focus on proportionate risk-based approach

- GCP E6 R3 to further advance this concept and to encourage relevant parties to utilize this approach:
  - Considering new trial designs, emerging technological innovations, different data sources, testing facilities and service providers or other emerging complexities of the current trial climate
  - Highlighting GCP principles can be satisfied in different ways - lean!
    - Think, ask why, agree on strategy, plan, do, check, act!
    - Document to assemble the trial story as evidence for compliance!

Answer 3

- GCP E6 R3 – content:
  - Principles documents and Annexes
    - Move away from checklist and audit police towards the ‘Spirit of GCP’
  - Align with ICH E8 (QbD)
    - Critical to Quality Factors (CQF)
    - Patient driven approach (involvement early - trial design)
  - Bridge gaps in E6 with other ICH guidelines
  - Clear and concise scope – expectations fit for purpose
  - Focus on key concepts. A few examples:
    - QbD & risk-based approach
    - Proportionality
    - Critical to quality factors

Answer 3

- GCP E6 R3 – content:
  - Overarching principles and Annex 1 Interventional Clinical Trials (traditional) developed in parallel – to replace R2 & developed first
    - IP used in a controlled setting with prospective allocation of treatment
    - GCP E6 R2 concepts and updates/refinements
  - Annex 2 Non-traditional Interventional Clinical Trials after Annex 1 is ready
    - Use of non-traditional clinical trial designs (pragmatic, decentralized, using real world data)
  - Technology:
    - Computerized systems, remote consent, telemedical monitoring

Answer 3

- GCP E6 R3 – current status and expected launch:
  - Drafting of principles
  - Stakeholder engagements with academic researchers & patient representatives
  - Annex 1 to replace R2 by end of 2021 …
  - Annex 2 expected by the end of 2022 …

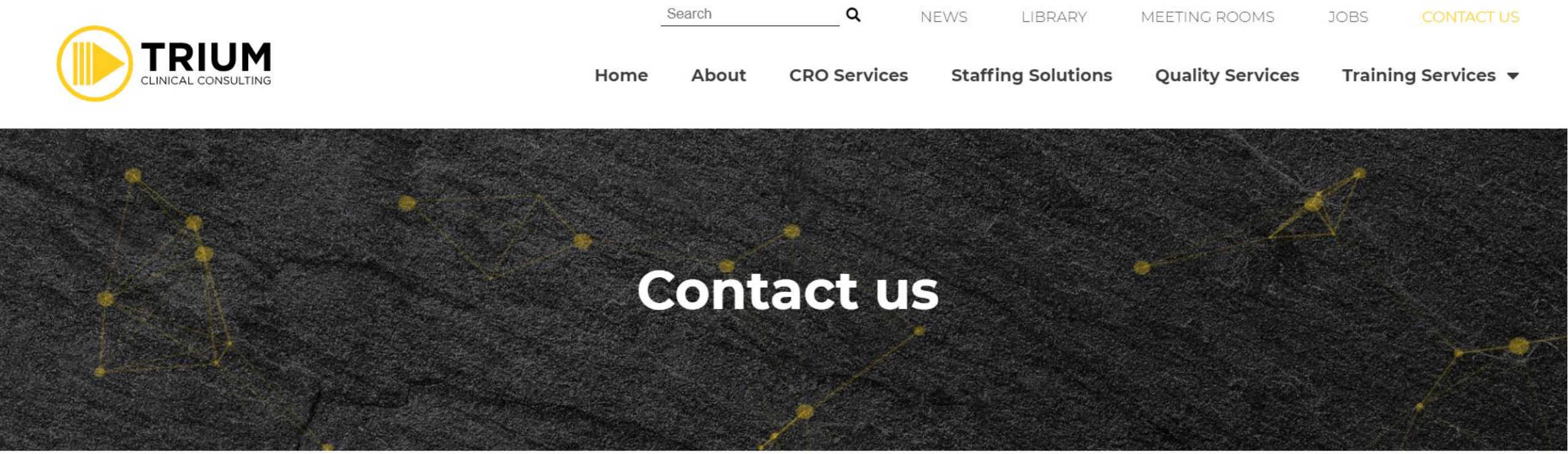
Learning Objectives

- By now, you should be able to:
  - Describe best practices in trial conduct post COVID-19 pandemic, ensuring subject safety and well-being, qualitative data and regulatory compliance
  - List the key changes between GCP E6 R2 and GCP E6 R3
  - Describe how GCP E6 R3 is supporting a new research framework that ensures better protection against disrupters like e.g. a virus pandemic

References

- ACRP, *The Impact of Increased Technology Use on the Clinical Research Workforce*, White Paper, April 2020
- Brookwood: *ICH GCP is changing* webinar, 15 Sept 2020
- CTTI, *Stakeholder Engagement on ICH E6 Guideline for GCP*, June 2020
- EFGCP: EFGCP Monthly Q&A Session - *Clinical Trials During the Corona Virus Pandemic: The Good, The Bad & The Ugly*, 07 Sept 2020
- Halloran Consulting Group Inc, *Adjusting To Clinical Trial Remote Monitoring During COVID-19: Working Smarter and Faster*, Todd Johnson and Hannah Yee, 10 April 2020
- ICH GCP E3: https://www.ich.org/page/efficacy-guidelines

Need help?



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