EFGCP Quality Working Party

For more information contact: louise@mirabilitas.com

Information in these slides constitute the collective shared experience of EFGCP Quality Working Party members and stakeholders participating in the EFGCP Covid webinar series; the views, thoughts, and opinions expressed in the Webinar solely to the authors, and not necessarily to any pharmaceutical company or contributing organisation.

1

Quality Working Party Experience

- Free COVID Webinar Series from April-20 – multi-stakeholder input
- Risk Assessment, SDV & Monitoring, Deviation Management, Statistical Analysis, Country Experiences (amongst others)

- **Initial Sponsor-driven Approach:**
  https://efgcp-events.eu/Clinical-Trials-COVID19-Repository.php
  - Risk-assessment process determining priority Projects & Studies
  - Acceptance not all studies can continue; evaluation of trial status
  - Evaluation of frequently published & updated country requirements, legal position, contractual impact
  - Alternative mechanisms for data & compliance monitoring explored
  - Gap analysis & remediation e.g. Site / Sponsor Staff Training
  - Looking to local resources for support (likely to be same/similar restrictions)
  - Inconsistencies in the monitoring completed by necessity – documentation essential

2

2

Quality Working Party Experience

- Realisation – Not going away any time soon
- More detailed trial and site-level risk assessments
  - Ongoing centralised data review (or centralised review introduced)
  - Detailed records of the type of monitoring by site, including changes over time
- Some site contact – telephone / email to establish status
  - Some sites relocated or limited by local hospital policy
  - Monitoring directed to eCRF, Essential Documents (ISF), SAE reports (non-SDV)
- Site-by-Site **feasibility** assessments (direct or via CRO) to look at SDV
  - Available technologies, resources, policies, legal requirements
  - Confidentiality Statements developed for use at each site 'visit'
  - Patient consent revisions & Patient communications
  - Tracking and monitoring of missing data, COVID-related deviations

3

3

Quality Working Party Experience

- Q3 2020 to Current – "New" Normal
  - Combinations of Centralised Data Monitoring, On-Site, Site Contact and Remote Monitoring proposed as standard
  - Where possible flexible monitoring schedules, adapted to site availability & access - Monitoring Plans describe the approach and Plan A, Plan B etc.
  - Focussed dataset for priority review e.g. AE/SAE information, protocol deviations
  - Contacts to site via mail/phone with increased frequency OR reduced frequency (local prevalence)
  - Remote contact – checks on IMP-supply, known deviations, Safety Data, COVID infections, e-Consent/Re-consent, patients transferred between sites
  - Distinction in records between remote *contact* & remote *monitoring* activities

4

4

Quality Working Party Experience

- Q3 2020 to Current – **"New" Normal**
- **Source Data Access**
  - 'Over the Shoulder' review by trial team, under guidance of Study Monitor
  - Redacted/Pseudonymised access to Health Records
  - On-site access available for some sites at some times (dependent on local viral prevalence)
  - Some sites possible to retrieve and relay records to an off-site location under Investigator's control (e.g. Hotel Meeting Room)
- **Challenges**
  - Time consuming
  - GDPR/Confidentiality indvidual site interpretations vary
  - Adequacy of Investigator & Sponsor Oversight
  - Qualfication of CROs / CRAs has not followed 'normal practice' from necessity Acknowlege extensive remonitoring will be needed in the future

5

5

Quality Working Party Experience

- Q4 Onwards – **Audit** Methodologies Piloted for Investigator Sites
  - Some models data-centric (no direct investigator involvement)
  - Some models reflective of monitoring approach (over-the-shoulder or using redacted data)
  - Some hybrid of the data-centric and monitoring – focussed on data query resolution from data review
- **Other Experience** (shared end 2020)
  - Investigators at Site – Challenging patient management – Need to use Vendors for IMP-supply (note consent implication), Variability in availability and access for electronic medical records
  - Data Monitoring Committees experiencing challenges with receipt of necessary data, data quality and Quorum for decision-making
  - Ethics Committees – guidance sought for many unexpected deviations and exceptions - "2020 Year of the Protocol Deviation"

6

6

Quality Working Party Experience

Forward Look?

- Embed methodologies for remote monitoring & audit
  - Central data monitoring routines ***as standard*** alongside other methodologies
  - Statistical monitoring on-top (support directed, risk-based review)
  - Detailed feasibility evaluations for technology, access, local requirements to support 'Virtual Visits', Decentralised Trials etc.
  - Using CROs with wide experience and available technologies (leverage their cross-trial / cross-sponsor / cross-country experience)
  - 'Virtual Visits' part of 'normal' activities – more inclusive for Sites, Patients?
  - Looking to design protocols with potential considerations
    - Limited windows only where necessary
    - Inclusion/exclusion criteria with consideration for COVID Vaccination (licensed/unlicensed)