Investigator Council presents: Insights

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ISCR'S ANNUAL CONFERENCE 2021 ANNOUNCEMENT

ISCR has announced its' fully virtual annual conference to be held from 19 to 20 March 2021 with a theme of **"Clinical Research – Transforming Lives: 2021 and Beyond",** preceding the main conference will be the pre-conference workshop from 12-13 March 2021**.** This conference will cover a variety of very relevant topics relating to the remote conduct and management of Clinical Trials including sessions on experience of investigator in the conduct of clinical trials during the pandemic, apart from other interesting topics. For more details regarding the conference, please visit: https://www.iscr.org/iscr-conference-2021/

INDIA'S COVID-19 VACCINATION PROGRAM STATUS

As we are all aware, India started a country wide COVID-19 vaccination program effective Jan 2021 with primary focus and prioritization given to the healthcare and frontline workforce. Till date (as on 17 Feb 2021) India has achieved a total vaccination count of 88,99,230. Most current updates and status can be obtained from https://www.mohfw.gov.in/

KEY TIPS AND GUIDANCE TO CONSIDER PRIOR TO & DURING COVID-19 VACCINATION FOR TRIAL SUBJECTS

As India has already stepped into the COVID-19 vaccination program across the country, the time is not far away when the common public will be undergoing vaccination based on defined priority in the country. Hence, there are a few tips to keep in mind when dealing with Clinical Trial patients at your hospital:

- Check protocol inclusion/exclusion criteria w.r.t vaccination or any additional memo or instructions from your Trial Sponsor or CRO.
- Enquire with patient about COVID-19 vaccination history or plans to get vaccinated.
- Investigator to evaluate risk-benefit assessment of COVID-19 vaccination based on trial subject's medical history and clinical condition.
- Reach out to your site CRA and Medical Monitor for any questions or guidance on vaccination.
- Document the vaccination details in subject source notes
- Closely monitor patient if vaccinated during the study
- Assess and record adverse events if any
- Follow CRF completion guidelines to capture the vaccine details in CRF

INVESTIGATOR SITE SOP TEMPLATES

Purpose of this Initiative:

- As we move towards an era of highly controlled Clinical Trial management, standardized methodology of conducting trials at Investigator sites is a key expectation from Indian Regulators. We at ISCR would like to support them by providing templates for preparation of SOPs which can be adapted as per site's need.

- These SOP templates have been carefully prepared by a wide range of Industry Experts including investigators and auditors to ascertain alignment with regulations governing clinical research in India.
    - Preparation, maintenance, and review of SOPs.
    - Audio Visual recording of Informed Consent.
    - Informed Consent Process.
    - Source Documentation at site.
    - Safety reporting & management by site.
    - Site Communications (EC, Sponsor & Regulatory).
    - Training of Clinical Study Staff.
    - Archival of completed studies.
    - SOP on subject compensation.

Please contact us at info@iscr.org for more information or to request for these SOP templates and to provide feedback on the templates.

INVESTIGATOR'S COLUMN: AN INTERVIEW ON "REMOTE DATA MONITORING"

Here we present excerpts from an interview conducted with Dr. Faraz Farishta, a renowned Endocrinologist and Director of Operations at FS Endocrinology & Diabetic Center and Consultant Thumbay Hospital, Hyderabad.

Topic of the interview: Remote Data Monitoring

Q1. In how many clinical trials have you experienced remote data monitoring at your site?
Response from Dr. Farishta: We had multiple Industry sponsored and academic Clinical Trials for which we had RDM during the pandemic.

Q2. What is your overall perception about RDM?
Response from Dr. Farishta: COVID-19 pandemic brought about a drastic shift and adoption of remote monitoring in Clinical Trials. It was then the most vital & only method to connect the site with the sponsor, and CRO ensuring adequate oversight and management of the trials in this phase with an intent to minimize impact to patients. Sites have been traditionally using paper-

based method and the pandemic brought about a cultural change & increase in dependency on digital methods & platform creating a paradigm shift in patient care & management which reduced lengthy work flow that could be managed with few clicks. By building digital network, Sponsor and Site started working efficiently which wasn't earlier in consideration or methodology to walk this path of working style with the following benefits:

a. Improved Utility and Convenience
b. Improved Efficiency: Adequate use of resources and time where we have been able to do at least 2 RDM per day which was never possible in person and would require days to finish the same.
c. Physical distancing
d. Access to needed and specific source document from anywhere - by digital connect, Sponsor and Site can access document from anywhere and at any time.
e. Adequate & channelized communication between Site and Sponsor - technologies that enable remote monitoring also streamlined communication like email documentation, notifications, in-app notification which has inbuilt reminders and alerts, ensuring improved efficiency.
f. Global tracking of study progress - when trials are transformed from paper to electronic, Site and Study progress can be captured on a real time basis; thereby improving visibility and data quality
g. E-Signature acceptance - increased acceptance of electronically signed documentation decreasing processing time of Site File related documentation.

Q3. Do you think it can replace on-site monitoring?

Response from Dr. Farishta: Both Onsite Monitoring and Remote Data Monitoring come with their own set of pros and cons. It is not possible to have one replace the other as they both would work in a complimentary manner.

a. Cons of On-site Monitoring:

- Expensive process
- Time consuming
- Rigidity around adopting newer methods and technology
- Could create issues with availability of dedicated space for monitors if multiple visits need to be accommodated.

b. Cons of RDM:

- Is not accessible for everyone unless EMR is adopted across sites
- Patients and doctors' skepticism with this approach due to risk of accidental breach of patient confidentiality (if the documents are not appropriately redacted prior to upload onto the online portal for remote access).
- Minimizes face to face interactions with site monitor which impedes rapport building between site staff and site monitor
- The need for additional customized healthcare software.
- Challenges in managing access to high volume of source document

Q4. What are the challenges you faced while setting up your site and then conducting for RDM?

Response from Dr. Farishta: Below are some of the main challenges faced during set-up and actual conduct of RDM at our site:

a. **Acceptability per site policies:** It was initially very difficult to convince the site for RDM as per the existing site SOPs but after explaining about the need to adapt according to the situation, it received acceptance.
b. **Resources:** In house training had to be done for the entire staff involved in the conduct of Clinical Trials.
c. **Technology** – use of EMR and providing remote access to the Site Monitor was again a challenge which was impinging on site's SOPs. Affirmation was given that no other data would be shared of other patients which would impinge on the data privacy.
d. **Lack of face to face conversation:** Monitoring the conduct of trial is recommended by ICH-GCP guidelines to maintain the quality and integrity of the conduct of trial. The connect between Sponsor and Site with face to face meetings always fulfils the need for a clear understanding of various aspects of the trial and trial related procedures. This also helped sites develop strong working relationship & invariably monitor is the first point of contact for the coordinator or any investigator for any question during the trial and vice versa
e. **Misunderstandings:** There were times that things were misinterpreted on virtual platform as there were pauses & language barriers in communication between the site and the monitor due to lack of face to face interactions.

Q5. In your opinion, how can we best utilise RDM for the larger goal of ensuring data quality and integrity and GCP compliance?

Response from Dr. Farishta: In the years to come I feel Hybrid model would be the best approach as it would be easier to connect and maintain better interpersonal relationship which is very important for the Sponsor and Site.

Sponsors need to train the Site Staff on the new technologies so that adaptations can be made easily. As I would say the change is only thing that is permanent in life.

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