Investigator Council presents: Insights

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ISCR'S ANNUAL CONFERENCE 2021 INVESTIGATOR SESSIONS SUMMARY

The first fully virtual annual ISCR conference was held from 19-20 March 2021 with a theme of **"Clinical Research – Transforming Lives: 2021 and Beyond",** preceding the main conference was the pre-conference workshop from 12-13 March 2021**.** This conference covered 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.

There was also an opportunity for virtual submissions of abstracts for oral and e-Poster Presentation, for original clinical research conducted and completed between 2018 to 2020. Clinical Researchers, faculty and students from Medicine, Pharmacy, Nursing and Biological sciences (post-graduate, under-graduate and super-specialty) participated in this event and winners were felicitated at the main conference.

As part of the main conference, there were 05 parallel tracks over 02 days (Clinical Operations, Ethics, Quality, Regulatory & Investigator, Academic Clinical Research and Real World Evidence, Clinical Data Management, Biostatistics and Statistical Programming, Medical Writing) with an entire track pertaining to Academic Clinical Research.

Some topics of interest from an investigator perspective, were the keynote address for the academic session titled building large academic networks for impactful research in India with National Cancer Grid as an example. The session also included short lectures about faculty-led research, academic research from a private hospital, collaborating for needs of country and making student-initiated research enjoyable and a life-changing experience.

The program included panel discussions on academia – industry collaboration that touched upon the factors required to make it a success for transforming lives of populations, also extensive discussions on building and nurturing clinician scientists in India.

Keeping in mind the current pandemic situation, an informative session on investigator's perspective regarding experience & challenges of managing studies during the COVID-19 pandemic was included in the agenda.

All in all, the conference was a star-studded event with experience sharing by regulatory, academia & industry stalwarts that was very well received by the audience.

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 and effective May 1, 2021, the vaccination drive has been expanded to cover all citizens above 18 years.

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Till date (as on 04 Jul 2021), India has achieved a total vaccination count of 35,12, 21,306 (total doses administered). Most current updates and status can be obtained from https://www.mohfw.gov.in/

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.

REMOTE DATA MONITORING (RDM) - A RECAP

International Regulatory Guidance on clinical trial management during the COVID-19 pandemic:

US FDA and MHRA have issued guidance (new and updated) for the industry that would be relevant for the management of studies during the COVID-19 pandemic. The details can be referenced via links below:

- https://www.fda.gov/media/136238/download
- Managing clinical trials during Coronavirus (COVID-19) - GOV.UK (www.gov.uk)
- Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency (fda.gov)

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A recap of RDM Pros & Cons summarized by Dr. Faraz Farishta, Endocrinologist and Director of Operations at FS Endocrinology & Diabetic Center and Consultant Thumbay Hospital, Hyderabad.

Benefits of RDM:

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.

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

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