Investigator Council presents: Insights

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THIS EDITION CONTAINS

- Pre-Conference workshop Summary – At K J Somaiya Medical college and hospital, Mumbai (23 Jan 2020)
- 13th Annual ISCR conference, Mumbai (24 – 25 Jan 2020) – key highlights from clinical operations track
- Shared investigator platform (SIP)
- Investigator site SOP templates

PRE-CONFERENCE WORKSHOP CONDUCTED AT K J SOMAIYA MEDICAL COLLEGE AND HOSPITAL DURING JAN 2020 – A BRIEF SUMMARY

Investigator Council (IC) in collaboration with K J Somaiya Medical College and Hospital, Mumbai successfully conducted an ISCR pre-conference workshop on 23 Jan 2020. Salient points about this workshop can be found below:

- The topic was "**Clinical Research: Enhancing Site and Investigator Capability Building**"
- It was attended by participants from various domains – Medical students, Clinical Research professionals, and CRCs (Clinical Research Coordinators).
- MMC credit points were available for the speakers and participants.
- The sessions were conducted by eminent and experienced speakers from various institutions and colleges.
- The session included a panel discussion that was enjoyed and appreciated by the participants.
- Overall the session was very well received with active participation from audience.

Few Moments captured during the pre-conference workshop

13TH ANNUAL ISCR CONFERENCE (MUMBAI, JAN 2020) KEY HIGHLIGHTS (CLINICAL OPERATIONS TRACK – I)

- ISCR conducted its' 13th Annual Conference at Mumbai from 24-25 Jan 2020 with a very enthusiastic participation from the Clinical Research Industry Representatives, Investigator Sites, Trial Subjects and Their Families, College Students, Pharma Companies, DCGI and US FDA Officials, Overseas SMO (Sri Lanka) and many others. The conference had 4 tracks: **Clinical Operations**, **Medical Writing**, **Data Management and Biostatistics.** The Clinical Operations Track agenda was focused around Increasing Participation and Enhancing Patient's Safety beyond new regulations.

Key topics covered during the two days conference in Clinical Operations Track are listed below:

- ICH-GCP Guidelines Harmonization – Experience sharing as "Expert Working Group Members" – an overview on ICH was provided with key focus around ICH-M11; ICH-E20 and ICH-E6 (R3) – the current challenges that R3 is targeting to address.
- Regulatory Audits and Inspections – Lessons Learnt from Site Audits and Inspections which also included a Q&A session wherein US FDA Inspectors clarified some of the expectations based on their inspection experience at Indian Investigator sites.
- Rotavirus Vaccine Development in India – An Investigator's Journey narrated by Dr. Gagandeep Kang.
- Approaches to Effective Oversight and Best Practices for Quality Management Between Sponsor and CRO Industry.
- Stem Cells in the Treatment of Disease – presented by Dr. Deepa Bhartiya from ICMR, Mumbai.
- Charting an International Career Journey – presented by PRA Health Sciences.
- Site Coordination, A Hospital Based Journey – presented by Rohini Hawaldar from Tata Memorial Hospital.
- Beyond New Regulations – Increasing Participation and Enhancing Patient's Safety.
- Capability Building Across Clinical Research Industry.
- Poster Presentations on several interesting topics from PhD students and Medical Doctors.
- There were several panel discussion sessions that provided ample opportunity for the audience to clarify questions directly with,

- The DCGI (Drugs Controller General of India) Official – Dr. V G Somani relating to:
  - Revised regulations,
  - Future on streamlining the Regulatory Review and Approval process,
  - EC Inspection Initiatives and several other topics.
- Principal Investigators on Critical Care/Terminal Illness trials relating to:
  - Challenges with identifying suitable trial subjects,
  - Patient care during and post-trial period,
  - Challenges with consent process,
  - Their expectations from CROs and Sponsors including regulators.
- Ethics Committee Secretary/Members on topics relating to:
  - Challenges on coping with their clinical trial review workload,
  - Plans for site audits,
  - Their own internal training process,
  - Adequacy of trained staff and other topics.
- Trial Subjects and their family members on topics relating to:
  - Their own or their family member's experience of being a trial subject,
  - Positive and Negative aspects of being in a clinical trial,
  - Challenges with consent process and the whole journey of being in a trial,
  - Post-trial access to treatment.

SHARED INVESTIGATOR PLATFORM

Shared Investigator Platform (SIP) is a system that was launched in 2016, which enables sites to collaborate with multiple sponsors through a single point of access, featuring harmonized content and services. SIP intends to introduce significant, far-reaching changes and improvements in how Pharma companies/CROs and sites work together. It will help in improving operational efficiencies and reduce effort and time.

Shared Investigator Platform (SIP) is hosted and supported by Cognizant, in partnership with TransCelerate BioPharma Inc. TransCelerate is a nonprofit group of the world's leading biopharmaceutical companies which has a vision of accelerating and simplifying research and development of innovative new therapies.

Currently clinical trial sites bear the administrative burden of using different platforms for communication and information sharing with different sponsor. These platforms require unique login ID and password. There is duplication of effort at the site level in sharing information / documents such as CVs/ GCP training certificates etc. with different sponsors.

Thus, a need for a centralized repository was recognized which will allow for harmonized sharing of information and will significantly bring down effort and administrative burden for the sites so that site personnel can concentrate on patient care.

The sites will have to login to a single portal with one username and password across multiple sponsors There will be mutually recognized Trainings across multiple Sponsors in SIP system.

SIP is an industry collaboration to streamline the clinical trial activities and data sharing between different stakeholders, e.g., Site and Sponsor for improved efficiencies. With SIP, sites can collaborate with sponsors and focus on patients by saving time on administrative repetitive activities. Sponsors can focus on their protocols rather than creating feasibility surveys. These small efficiencies can result in achieving faster end results overall.

The sponsors who are part of SIP initiative will have read only access to the user profile information of all registered site users, but not to the data specific to the clinical trials. More information regarding SIP can be obtained from following link:
https://www.sharedinvestigator.com/home

INVESTIGATOR SITE SOP TEMPLATES

Purpose of this Initiative:

- Investigators and Clinical Research Sites are pivotal to "Clinical Trial" conduct to bring innovative drugs to market. 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 and Indian Regulations. We at ISCR would like to support them by providing templates for preparation of Standard Operating Procedures which can be adapted as per site's need.
- This is particularly essential and helpful when we want new clinical sites to be developed as well as when some of the well-established ones want to keep themselves updated with some of the best practices used across the industry.
- The current available templates have been carefully drafted and reviewed by wide range of Industry Experts including investigators and auditors to ascertain most acceptable practices and needs so as to align with most recent 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 these SOP templates and to provide feedback on the templates.