Investigator Council presents: Insights

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THIS EDITION CONTAINS

ISCR'S AUTUMN CONFERENCE ON "CLINICAL RESEARCH LANDSCAPE – POST 2020"

ISCR successfully organized first of its kind fully virtual Autumn Conference for 2 days from 09 to 10 Oct 2020 with very active participation of representatives from across the industry including Research Investigators, Ethics Committees Members, Pharmaceutical Organizations, CROs, Students as well as speakers from overseas. The key focus and intention of this conference was to look at the changing landscape in Clinical Research in the current scenario wherein the entire globe is faced with the challenge of dealing with COVID-19 pandemic and its related impact.

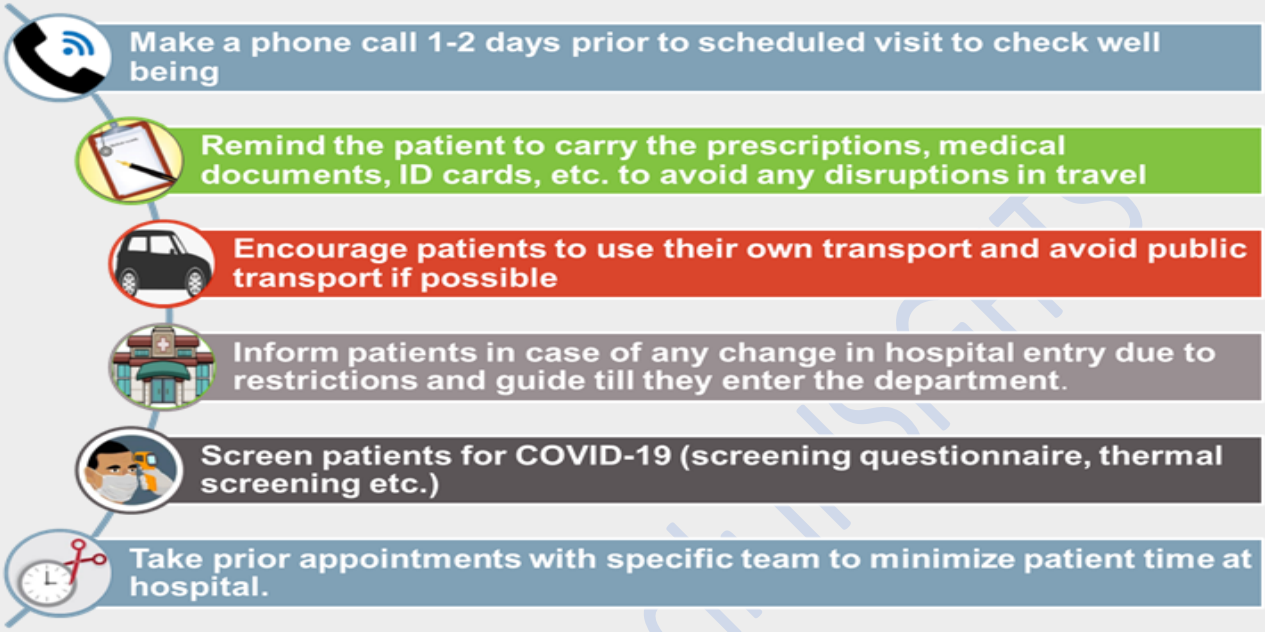
For details on the topics covered and speakers, please refer to:
https://www.iscr.org/indian-clinical-research-past-events

GUIDELINES ON DEVELOPMENT, EMERGENCY USE AUTHORIZATION AND LICENSURE OF VACCINES DURING COVID-19 ERA

US FDA and CDSCO have recently issued guidelines for the industry on Development, Emergency Use Authorization and Licensure of vaccines in the COVID-19 era during Sep-Oct 2020. The details can be referenced via below links:

- FDA Guidance for Industry October 2020 - Emergency Use Authorization for Vaccines to Prevent COVID-19: https://www.fda.gov/media/142749/download
- FDA Guidance for Industry June 2020 - Development and Licensure of Vaccines to Prevent COVID-19: https://www.fda.gov/media/139638/download
- CDSCO Notice for Vaccine Guidelines dated 21-Sep-2020: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ5OQ==
- CDSCO Regulatory guidelines for development of Vaccine 21-Sep-2020: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjUwMA==

RECOMMENDED BEST PRACTICES WHILE RESUMING PATIENT AND TRIAL MANAGEMENT DURING UNLOCK



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 and Indian Regulations. We at ISCR would like to support them by providing templates for preparation of SOP's 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 SAFETY REVIEWS BY PRINCIPAL INVESTIGATOR

Here we present excerpts from an interview conducted by Investigator Council member, Dr. Karan Thakkar with Dr. Pawan Kumar Singh. Dr. Singh is the Head & Senior Consultant, Haemato-Oncology & BMT at Artemis Hospital, Gurgaon, and has been the Principal Investigator on several global Clinical Trials.

Topic of the interview: Safety Reviews by Principal Investigator during a Clinical Trial.

1. Do you conduct a periodic review of the SAEs occurring at your site?
Dr. Pawan Kumar Singh: Yes, we conduct a periodic review of all safety data from our ongoing Clinical Trials. The frequency depends on the type of trial, whether the IP is new or already approved molecule, the frequency and total number of Adverse Events being reported to DCGI after meeting with internal committee or feedback from sponsor's DSMB (Drug Safety Monitoring Board), etc. We have these discussions with our entire team including Sub-Investigators and Site Coordinators.
The EC also conducts a routine review of safety data and then asks the investigator to present this and discuss in context of Protocol, IB, and current medical practices.

2. How do you approach causality assessment for SAEs?
Dr. Pawan Kumar Singh: This depends on:

a) Patient's diagnosis and co-morbid conditions
b) Mechanism of action of drug
c) Time relation to drug administration and other concomitant therapy or associated factors.
d) Already available information in protocol and IB.
e) Any new event is also reported to EC, DCGI and Sponsor.

3. How does the site review, discuss and notify SUSARs?
Dr. Pawan Kumar Singh: Different Sponsors have different methods to provide us with SUSAR reports. Some provide them electronically via online systems. In such cases, we can login and then review/ download the reports.
In all cases, these reports are discussed with the team and then notified to the EC.

4. What is your practice for protocol specified adverse events or events which are to be reported as endpoints and not AEs?
Dr. Pawan Kumar Singh: We follow the country regulations and report SAE if the event meets the SAE criteria. If there is any doubt we discuss with Sponsors. We report such doubtful events as initial reports within 24 hours of awareness and if there is some change in reporting requirement, we update in the detailed report to be sent within 14 days. We also notify EC as required by EC - SOP and regulations. We make sure to have such discussions with Sponsors at the time of SIV so that expectations can be clear.

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