Investigator Council presents: Insights

Volume 11, November 2020
Become a member of ISCR, contact us at info@iscr.org

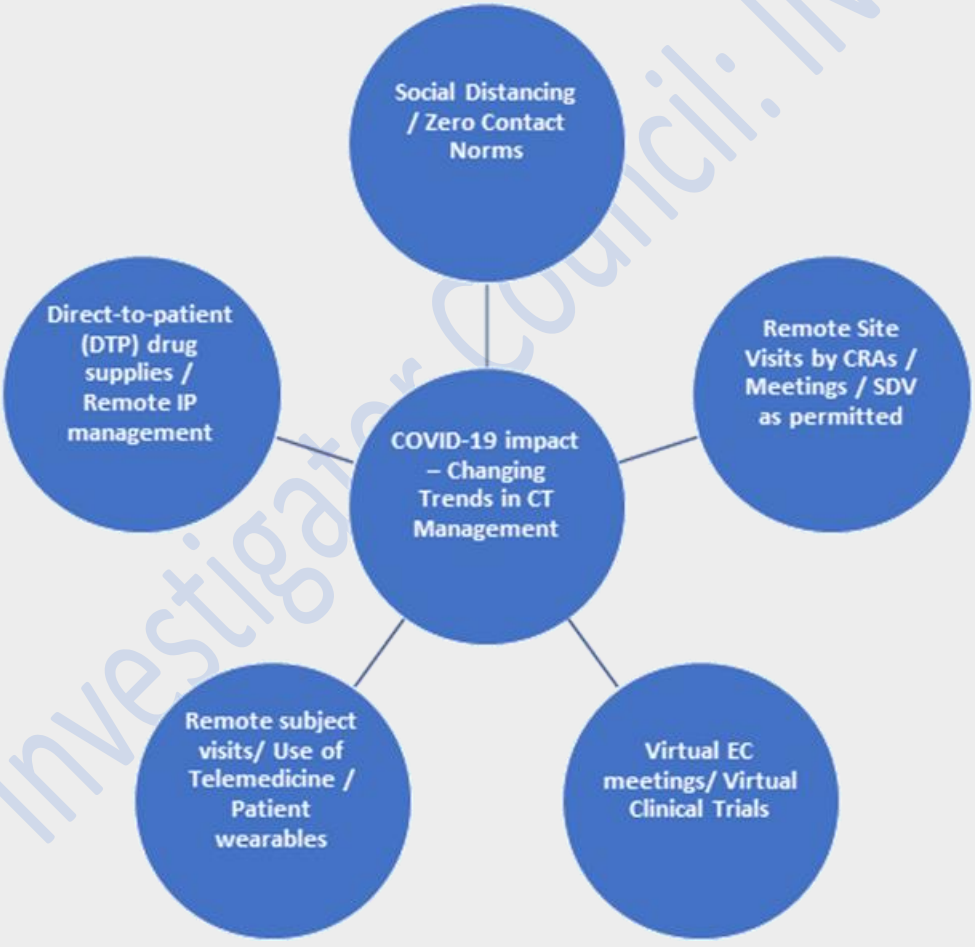
THIS EDITION CONTAINS

ISCR'S ANNUAL CONFERENCE 2021 ANNOUNCEMENT

ISCR has announced its' fully virtual annual conference to be held in mid-March 2021 with a theme of **"Clinical Research – Transforming Lives: 2021 and Beyond".**
Watch out this column for more information to follow in subsequent editions during 2021.

CHANGING TRENDS IN COVID-19 ERA

COVID-19 has changed the way clinical trials are conducted, as demonstrated below, ensuring that subject safety and data integrity remain of paramount importance:



CLINICAL TRIALS – A GUIDE FOR PARTICIPANTS

ISCR has issued a guidance document in public interest to answer some of the key questions that run around each participant when considering participation in a Clinical Trial. It is a very simple, informative and easy to comprehend document that is available in 8 local languages apart from English and can be accessed via following link: https://www.iscr.org/patient-leaflets/

The main topics covered in this guidance document include answers to the most asked top 10 questions:

- What is a Clinical Trial?
- Why should it take part in a Clinical Trial?
- Who is eligible to take part in a Clinical Trial?
- Does a person have to have an illness to take part in a Clinical Trial?
- How can a patient take part in a Clinical Trial?
- What kind of information should a participant before deciding to take part in a Clinical Trial?
- What is the Informed Consent Process?
- How are patient rights protected?
- Can a patient stop taking part in a trial midway?
- Are people paid for participating in a Clinical Trial?

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 "COMPENSATION TO CLINICAL TRIAL PARTICIPANTS"

Here we present excerpts from an interview conducted with Dr. Rajesh Khadgawat, Dr. Khadgawat is Professor Department of Endocrinology and Metabolism at AIIMS, New Delhi and Dr. Jayaprakash Appajigol, Dr. Appajigol is an Associate Professor and General Physician as KLE Hospital, Belgaum. They have been the Principal Investigator on global Clinical Trials.

Topic of the interview: Compensation to Clinical Trial Participants.

Q1. When do you have discussion on compensation and free medical management with your clinical trial participants?
Response from Dr. Khadgawat: These issues are discussed in detail with subjects during consent process discussion as they are covered within the Subject Information Sheet and clarified prior to the subject signing the ICF.
Response from Dr. Appajigol: Discussed in detail during the Consent process and re-discussed whenever an SAE occurs that maybe possibly related to the study drug.

Q2. Please describe the key elements that you highlight when having this discussion with participants?
Response from Dr. Khadgawat: We discuss all aspects as specified by EC and per our regulations.
Response from Dr. Appajigol: We explainregarding Insurance policies, Compensation and free medical management (if an SAE occurs, sponsor will bear medical management till its proven relatedness with IP).
Note: Per Clinical Trials Rules 2019, it is described as,
"Where an injury occurs to any subject during clinical trial or bioavailability and bioequivalence study of a new drug or an investigational new drug, the sponsor, shall provide free medical management to such subject as long as required as per the opinion of investigator or till such time it is established that the injury is not related to the clinical trial or bioavailability or bioequivalence study, as the case may be, whichever is earlier"

Q3. Do you proactively review and discuss the applicable compensation and/or free medical management for your clinical trial participants with your EC?
Response from Dr. Khadgawat: Yes, because it is also an EC requirement to have this discussion and provide details for the trial under their consideration
Response from Dr. Appajigol: Yes

Q4. What mechanism do you follow to seek reimbursement of medical management costs or compensation in applicable cases?
Response from Dr. Khadgawat: Reimbursement of cost of treatment is as per actuals/bills submitted by the patient while compensation is decided by EC/DCGI in case of death and non-fatal SAEs. These are part of DCGI regulations.
Response from Dr. Appajigol: As per the NDCTR (New Drugs and Clinical Trial Rules) 2019.

BEST WISHES AND OUR MESSAGE AS WE STEP INTO 2021

As the year 2020 leaves us with one of the worst hit pandemic memories while the world continues to cope up with it even now and as we look forward to step into the New Year 2021, this year has possibly also been the year of great learning and positivity that we should cherish upon as we advance towards 2021:

- The pandemic has brought the globe together as one large family.
- People have learnt new ways of conducting themselves as well as the business.
- People have begun to realize the importance of maintaining good health much more than ever before.
- Acceleration in drug development (novel therapies as well as re-purposing of existing therapies), including expedited vaccine trials.
- Change the way Clinical Trials will possibly be conducted in future.

We would like to take a moment to pay homage and tribute to all those who lost their lives to this pandemic and our salute to the unsung heroes from all walks of life who continue to serve the society during this pandemic and tirelessly work towards getting the world a step closer to successful preventive and therapeutic strategies for combating this pandemic.

"Merry Christmas
&
A Very Happy New Year 2021 from Investigator Council"

****