Subject: ISCR is set to launch workstreams towards bringing out Whitepaper on "Decentralized Clinical Trials in India" and You are invited to contribute!

Dear Members,

Background:

Decentralized clinical trials (DCTs) have quickly become a strategic priority for clinical trials, one that is expected to endure in the post COVID-19 pandemic period. Once viewed as nice-to-have pilot projects, DCTs—trials conducted remotely or through local healthcare providers to improve the patient experience are becoming more mainstream. While drug-based interventional DCTs only experienced a 7% CAGR between 2014 and 2019, they jumped to 77% between the second halves of 2019 and 2020 after the onset of COVID-19. While the regulatory agencies which are more mature are enacting regulations and guidelines on DCTs, India is definitely lagging behind. Many of the trials that are now coming through as part of Global Clinical Trials are having some element(s) of DCT included and we need to build the ecosystem for the same at the level of all stakeholders - Regulators/EC members/sponsor-CRO/Investigator-Site and Patients. ISCR is planning a white paper on Decentralized Trials/Virtual Trials in order to provide clarity on the varied capabilities, current state, challenges and opportunities in India. This email and the google registration form at the bottom of the email is an invitation to AMO representatives and lifetime members to contribute to developing the White paper.

Details regarding the Workstream

- Duration of workstream = 3 mths + 1 mths of report writing
- WS launch End August 2021 ; duration Sept - Oct- Nov; publishing in Nov/Dec 2021
- Open to all AMO (AMO needs to provide some justification of why the member can be part of the workstream and need not be based on seniority) + ISCR Life time members (can be part of only one workstream but need to provide justification [knowledge, work experience etc.] of why the member can be part of the workstream);
- Microsoft sharepoint platform will be used as document repository for the authoring of the Whitepaper

Specific DCT Capability and workstreams	**ISCR Executive Committee Sponsor**
Telemedicine in clinical trials	Ramesh Jagannathan

e-consent, e -signature (for consent, CDA,CTA)	Chirag Trivedi
Direct To Patient -Medicinal Product; Site to Patient home, Depot to patient home	Anirban R Chowdhury/Sanish Davis
Home Health Care(home nursing in clinical trials)	Kedar Nayak
remote SDV/ remote SDR (virtual monitoring), targeted SDV/SDR, Remote SIV, Remote Investigator Site File	Suneela Thatte
e Clinical Assessments (PRO, others)	Seema Pai
Digital & Social Media patient recruitment	Melissa Arulappan
Patient Centricity (what is the patient's perspective)	Sachin Tonapi
Remote Data Capture (ECGs, CGM etc.), Wearables, Digital Biomarkers	Deepa Chodankar
Data Security, Data Privacy, Ethical considerations	Muruganathan K

Here are some of the **Areas/Issues/Perspectives** that needs to be brought forth in the planned Whitepaper for each of the capabilities.

- Definitions, what does this capability mean?
- Mapping the current landscape for this capability globally and in India.
- What solutions are available for this capability globally and in India? Current state vs. Desired state from an infrastructure perspective.
- What is the regulatory approach/environment for this capability in India?
- Are there any India specific Legal challenges anticipated (e.g. e-signatures)?
- What are some of the key technology challenges in implementing this capability in India?
- Any EC/IRB challenges anticipated from an Indian perspective?
- What are some of the challenges at the investigator/site level (e.g. capacity, understanding, execution)?
- What are Institutions/Pharma companies/CROs doing in this area?
- What is the Patient's view on DCT?
- What is the downstream benefits for the capability? E.g. Make in India?
- Recommendations for this capability in India (max. 3-5 pragmatic and implementable recommendations)

Further actions and dates for your attention:

1. AMOs can nominate their representatives for each of the Workstream and so can ISCR Lifetime members. You are requested to send your AMO representative/your individual nominations by the **25th** of August after which the registration link will close. Both AMO Representatives (nominees) and lifetime members should provide details on how the nominee/member can contribute [knowledge, work experience etc.].
2. Please use the google form to register/nominate : https://forms.gle/pZb4XcrrUHgw5Bd36
3. Nominations (either by AMOs / AMO representatives / ISCR Lifetime members) without the justification details will not be entertained by the workstream sponsors.
4. We will have a kick off meeting for the workstream on the 30th and 31st of August (5-530 pm). If you are selected to a workstream you will be intimated about this meeting closer to the meeting date but no later than the 27th of this month.

For any query or further information please feel free to write to info@iscr.org or SDavis20@its.jnj.com.

Thanks and Regards,

ISCR Executive Committee (2021-23)