Indian Society for Clinical Research
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10 February 2015

To,

The Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla road,
New Delhi -110002

Subject: ISCR suggestions on Notice dated 28-January 2015

"Pre-submission Meetings-(Regulatory Pathways)"

Respected Sir,

This is with reference to the notice dated 28-January 2015 on 'Pre-submission meetings- (Regulatory Pathways)" put up on the website for stakeholder comments and suggestions.

Firstly, ISCR would like to acknowledge CDSCO for introducing this new and much awaited process. While we thank you and your staff to hold meetings and engage with us for such discussions on need basis; it is a step in the right direction to have a formal process and structure in place for such important meetings. We welcome salient features such as the **meetings to be voluntary** and **maintenance of confidentiality** as outlined in the proposal. This will not only provide flexibility to the stakeholder to consult with the regulator only on need basis thereby optimizing time spent by both but also ensure that the meeting proceedings remain confined between the two parties only and not available in public domain for potential misuse. **Therefore, would like to reiterate that these two features be retained.**

Like all processes, this new process will also will need to make the evolutionary journey. We would like to volunteer to write a process flow for the pre-submission exercise, if CDSCO requires one.

Listed below are three suggestions that we believe will help strengthen this effort and make this a valuable tool to all. ISCR would be happy to partner with CDSCO and help to put the necessary framework and detailing to the new process that would address following points.

1. Include broad timelines for the various stages of the procedure starting from the applicant's request till issuance of the meeting minutes.
2. Issue general guidance on the type of information and the format in which these need to be submitted for such meetings.
3. Refer global best practices of advanced regulatory bodies to avoid re-inventing the wheel and align Indian process to these.

We look forward to having this process implemented. Please feel free to contact us if there are any questions or comments.

Thank you,

Yours sincerely,
Dr. Shashwati Pramanik
Co-Chair Regulatory Council
Indian Society for Clinical Research