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The **ISCR or Indian Society for Clinical Research** is an association of clinical research professionals registered under the Societies Registration Act (1860). It brings together those engaged in clinical research activities in India and provides a forum for exchange of information and learning. ISCR aims to build awareness of clinical research as a specialty and facilitate its growth in the country, while helping to evolve the highest standards of quality and ethics.

ISCR's mission is to inspire and align diverse stakeholders to shape and foster an environment facilitating ethical and responsible clinical research for better patient outcomes.

The primary **objectives** of ISCR are:

- Generation awareness about clinical research as a specialty, and of its scope, intricacies, and potential in India.
- Establishment of a forum for exchange of learning and for imparting training to new entrants to the field.
- Creation of a repository of information on Clinical Research in India that will be available on the Internet.
- Facilitation of growth of clinical research in India by monitoring clinical research activity, providing review and peer consultation facilities for research projects, and representing to government and other agencies on behalf of the clinical research community.

## **Membership**

Membership is open to all teaching and medical institutions, companies and individuals involved in clinical research and allied activities. Primarily, membership consists of two categories:

- Accredited Member Organizations (AMOs) and
- Individual Membership

Members can participate in various activities of the society, obtain information on clinical research in India, get in touch with suppliers and vendors of equipment and communicate with each other.

## **Current Activities**

ISCR has seven functioning councils which constitute the major activities of the Society. Each of the Councils has a Council Chair and Members who drive the respective agenda of the Councils, guided by the overall objectives and mission of ISCR. The seven Councils are CDM, BS and MW Council, Ethics Council, Investigator Council, Media Council, Pharmacovigilance Council, Regulatory Council and Training Council.

The objectives of the **Clinical Data Management, Biostatistics and Medical (CDM, BS & MW) Council** are to:

- Create awareness about CDM, BS & MW among various stakeholders
- Share new developments through the website and interactive events
- Conduct training programs in CDM, BS & MW to help members enhance knowledge
- Create awareness about the latest regulations, evolving global technologies and roles of CDM, BS & MW professionals and the impact of these on the entire clinical trial process.

The **Ethics Council** endeavors to

- Increase awareness and support discussion on ethical aspects within the clinical research fraternity and contribute to safeguarding the dignity, rights, safety and well-being of all trial participants
- Provide a useful framework for understanding the principles of ethics which is respect for human dignity, autonomy, informed consent, vulnerable persons, confidentiality, the lack of harm, maximum benefit and justice.

The **Investigator Council** which comprises key opinion leaders and highly experienced clinical trial investigators is focused on:

- Generating awareness of clinical research among the investigator community and capacity building for potential Investigators in India
- Working with investigators across India to propagate adoption of the highest standards of clinical research at investigator sites by providing the required guidance and training
- Creating a medium to communicate issues, concerns and expectations from research sites to ISCR and further to regulators and policy makers through appropriate channels.
- Providing a platform to team members to discuss issues and exchange best practices.

The **Media Council** strategically positions ISCR on key issues concerning image and perception of clinical research in India. It is engaged in:

- Accurately portraying the image of clinical research in the country
- Communicating the role and relevance of clinical research in the country
- Providing communication tools such as the ISCR website as a one stop knowledge portal/solution for the clinical research community
- Continuing professional development for the clinical research community in India through the flagship publication for ISCR, Perspectives in Clinical Research (PICR).

The **Pharmacovigilance Council** aims to:

- Emphasise the importance of Pharmacovigilance in every phase that the pharmaceutical industry is involved in
- Extend support to and collaborate with regulators and other stakeholders to have alignment in practices followed
- Develop high quality training materials and fora to inculcate the culture of reporting in various stakeholders.

The **Regulatory Council** endeavors to

- Establish a rapport with key regulators involved in policy making/regulations involving clinical research in the country so that the voice of the clinical research fraternity is appropriately articulated to the decision makers. These include the Office of the DCGI, as also other influential sections within the government particularly ICMR, senior bureaucrats associated with the Health Ministry, etc.
- Conduct regular innovative training programs for those primarily engaged in the regulatory aspects of clinical trial applications, namely filings and approvals.

The **Training Council** aims:

- To help in capacity building of clinical research professionals in various related topics
- Generate high quality training programs addressing existing knowledge and skills gaps
- Create a network of highly trained professionals.
- Work towards certification of key roles in clinical research.

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