FREQUENTLY ASKED QUESTIONSONS ON CLINICAL RESEARCH USING STEM CELLS

1) Do stem cells fall under the category of 'drug'?

- Stem cells and their derivatives fall under definition of 'Drug' as per the Drugs and Cosmetics Act 1940, and are categorized as 'Investigational New Drug (IND)' or 'Investigational New Entity (INE)' when used for clinical application.
- Hence clinical trials are a must before these can be applied for any unproven applications and the principles of bioethics and regulation must be followed accordingly before initiating clinical trials.

2) What is Clinical research/study/ trial?

- Clinical research/study/trial test capability of treatments in human volunteers or patients to see whether they should be further investigated or commercially used in general population.
- A treatment could be a drug (medicine), medical device, or a stem cells, vaccine, blood product, or gene therapy.

It must be noted that participants of a clinical trials can't be charged for the trial treatment they are getting.

3) Why clinical trials are important?

- Often, a promising lead in the lab does not translate into a safe and effective treatment for humans.
- There may be several risks and side effects associated with the administration of new drug/product/process in humans. Thus any new drug/products/process requires a thorough evaluation in the form of a well designed clinical trial.
- Any ill effects that can be caused by a new drug/products/process can only be known when the patients are followed up for appropriate period which can only be done in a clinical trial.

4) Have there been stem cell clinical trials in India? What have been the results?

- Yes, different Government agencies like ICMR, DBT, DST etc have funded and are funding stem cell related clinical trials.
- The experience of Indian funding agencies so far has shown that stem cell therapy is yet not an effective option in several conditions.
- The pilot studies supported in spinal cord injury and age related macular disorder did not show any benefits of stem cell treatment.
- Similarly, multicentric trials in chronic stroke and myocardial infarction did not show statistically significant improvement.
- However, exceptional results/positive trends have been obtained in critical limb ischemia caused by Burger's disease and that has been granted conditional approval by CDSCO to substantiate the outcome by doing more cases.

5) Which agency regulates clinical trials in India?

All clinical trials are regulated by CDSCO and require prior approval of DCG(I) before they can be started.

6) Is there a difference between clinical trial and clinical practice?

Yes.

- In clinical practice specialised doctors uses established treatments.
- In clinical trial proof/evidences are collected in scientific and ethical manner to establish a treatment.

7) Which institutions/hospitals can conduct clinical trials?

As per NGSCR 2017, only those entities that fulfill the following requirements defined in NGSCR, 2017, can conduct clinical trial with stem cell:

a. Clinical trials can be permitted only in institutions/hospitals having registered IC-SCR (with NAC-SCRT) and IEC (with CDSCO). For multi-centric clinical trials, all participating sites should obtain approvals form their own IC-SCR and IEC.
b. These can only be conducted in a medical institution/hospital with adequate infrastructure and clinical facilities in accordance with Para 2 (1)(ii) of Schedule Y, Drugs and Cosmetic Act 1940 and Rules 1945.

8) What are the requirements for stem cell clinical trials?

a. Clinical trials should be in compliance with Schedule Y of Drugs and Cosmetics Act and GCP

Guidelines of CDSCO (www.cdsco.nic.in) as well as ICMR-Ethical Guidelines for Biomedical and Health Research involving Human participants 2017 http://www.icmr.nic.in/ethical_guidelines.pdf

b. All clinical trials on stem cells shall be registered with Clinical Trial Registry India (CTRI). http://ctri.nic.in/Clinicaltrials/login.php
c. The cells or cell-based products used in the trial should be processed in a CDSCO certified GLP and GMP facility (Schedule L1 and M of Drugs and Cosmetic Act, 1940 and Drugs and Cosmetics Rules, 1945.
d. Clinical trial must have a medical specialist registered with MCI and holding MCI approved post graduate qualification in the subject domain of the trial.
e. All medical professionals involved in clinical trials should have a valid GCP certification.

9) **Who can participate in a clinical trial?**

Any patient/ healthy person who match the requirement of the given trial can participate.

10) **Can a patient be charged if he is participating in a clinical trial?There are several clinics/hospitals that claim to be doing clinical trials, but ask for money, is that OK.**

- No, participants enrolled for clinical trials are liable to pay any charges towards procedures, investigations and/or hospitalization related to the trial.

11) **How to participate in a study?**

- ICMR will soon start a portal for such information. Till then, CTRI site can be checked for ongoing trials in the field.
- For international trials, following link listing the international trials registries in different countries can be referred tohttps://www.hhs.gov/ohrp/international/clinical-trial-registries/index.html .

12) **From where do the cells used in clinical trials come from?**

- The stem cells transplanted into patient can be from his/her own body (known as 'autologous' transplant) or
- Non-self source (known as allogeneic transplant) which include fetal, embryonic, cadaver or a living donor. The donor or the tissues first need to be checked for matching before it can be given to the patient.
- It is important that prior video consent of donor is obtained for procurement of biological material for research or allogenic transplant.

Please refer to NGSCR 2017 for complete information on the requirements for conduct of stem cell clinical trials in India.