Media report “National Guidelines for Gene Therapy Product Development and Clinical Trials”
Preface

The PR Unit/PRO office of ICMR since last one and half years have reached from (where is ICMR located) to (everyday mention of ICMR and DG ICMR in National Media). This change from where to why signifies the media visibility and importance of our organization within this stipulated time duration.

This report regarding “National Guidelines for Gene Therapy Product Development and Clinical Trials” features the media/news coverage provided by national and regional media of the country such as The Times of India, Deccan Herald, The Hindu Business Line among others.

Syed Adil Shamim Andrabi
Information Interface Officer/PRO
ICMR Hqrs, New Delhi
ICMR comes up with guidelines for gene therapy product development, clinical trials
December 13, 2019/The Times of India

ICMR releases rules to pave way for novel gene therapy
December 13, 2019/Deccan Herald

ICMR releases draft guidelines to treat rare genetic diseases
December 13, 2019/Live Mint

ICMR releases draft guidelines to treat rare genetic diseases
December 13, 2019/New Kerla

ICMR issues guidelines for gene therapy in India
December 13, 2019/Outlook India

ICMR Issues Guidelines For Gene Therapy In India
December 13, 2019/Republic India

ICMR issues guidelines for gene therapy in India
December 13, 2019/Business Standard

ICMR issues guidelines for gene therapy in India
December 13, 2019/DT Next

ICMR releases draft guidelines to treat rare genetic diseases
December 13, 2019/ANI News

ICMR sets up a task force on gene therapy research
December 14, 2019/The Hindu Business Line

ICMR releases gene therapy, clinical trials guidelines
December 14, 2019/Drug Today Medical Times
ICMR comes up with guidelines for gene therapy product development, clinical trials
December 13, 2019/The Times of India

With an aim to ensure better treatment options for 'rare diseases' or inherited genetic diseases such as Gaucher's disease, haemophilia, thalassemia, sickle-cell anaemia and certain forms of muscular dystrophies, the Indian Council of Medical Research (ICMR) has come up with the national guidelines for gene therapy product development and clinical trials. The idea is to promote gene therapies in India and ensure clinical trials for gene therapies can be performed in an ethical, scientific and safe manner. “These are modern and robust guidelines, and are pragmatic for the country. These guidelines will provide the general principles for developing gene therapy products for any human ailment along with the framework for human clinical trials,” ICMR Director General Balram Bhargava said. Around 70 million Indians are estimated to suffer from rare diseases in India. However, experts say the data is inadequate to give away the actual burden. Bhargava said both the Prime Minister’s Office (PMO) and NITI Aayog were keen on having these guidelines in place and pushed to fast track the process. The guidelines are expected to serve as an important resource and roadmap for development of gene and cell therapies. “We hope this will spur innovation and accelerate research into rare diseases in our nation,” ICMR said.

ICMR releases rules to pave way for novel gene therapy
December 13, 2019/Deccan Herald

Nine months after the national drug regulator CDSCO recognised “gene therapy” as a new drug, Indian Council of Medical Research has come out with the first guideline for the industry and research establishment on how to make such products on the basis of sound ethical, scientific and regulatory norms. The guidelines not only outlines the ethical and scientific requirements for gene therapy trials but also asks developers to keep the patient’s safety, efficacy and clinical rigour in mind while developing such therapies. Two other types of therapies involve knocking out a bad gene that triggers disease and introducing a new gene to fight disease. The first successful gene therapy clinical trial was conducted in 1989 in the USA, for severe combined immunodeficiency. “In India, there is no gene therapy trials yet. Along with guideline, the ICMR has also sought proposals from researchers for funding opportunities for gene therapy projects targeting human disease,” Geeta Jotwani, programme coordinator for gene therapy and gene editing at the ICMR told DH. The apex medical research council looks at gene therapy as a treatment option not only for inherited diseases and rare diseases but also for multi-factorial ailments like cancer, diabetes, lung diseases and neurological diseases. Several Indian pharmaceutical companies have shown interest in a particular gene-therapy for cancer known as Car-T cell therapy, in which one particular immune cell of a patient (T-cell) is tweaked using gene therapy in such a manner so that they attack and kill cancer cells.
ICMR releases draft guidelines to treat rare genetic diseases
December 13, 2019/Live Mint

In a bid to attract the pharmaceutical industry for pooling investments in drugs for treating rare diseases, country’s apex research body Indian Council of Medical Research (ICMR) has come up with national guidelines for gene therapy related clinical trials. With the document called as the “National Guidelines for Gene Therapy Product Development and Clinical Trials”, the government aims to ensure that the gene therapies can be introduced in India and their clinical trials can be performed in an ethical, scientific and safe manner. Also, spur innovation and accelerate research for rare diseases. Inherited genetic diseases or rare diseases refer to medical conditions that affect a small percentage of the population but has vast, debilitating and often life threatening effects of the patients, many of whom are in the paediatric age group. “Treatments for such diseases have long been neglected by the traditional pharmaceutical industry because of the notion that it will have uncertain or poor commercial outcomes given the smaller affected population size," ICMR said in an official statement. According to ministry of health and family welfare, cumulatively, approximately 70 million Indians suffer from some form of rare disease. These include haemophilia, thalassemia, sickle-cell anaemia certain forms of muscular dystrophies, retinal dystrophies such as retinitis pigmentosa, corneal dystrophies, primary immunodeficiency (PID) in children, lysosomal storage disorders such as Pompe disease, Gaucher’s disease, haemangioma, cystic fibrosis etc.

ICMR releases draft guidelines to treat rare genetic diseases
December 13, 2019/New Kerla

The Indian Council of Medical Research (ICMR) on Friday released the draft guidelines for ensuring that rare genetic therapies and clinical trials can be performed in an ethical, scientific and safe manner in India. "National guidelines for the treatment of patients suffering from rare genetic diseases" will assist medical experts to get genetic therapy product development and conduct clinical trials. About 70 million Indians suffer from inherited genetic diseases or ‘rare diseases' (RD), according to the apex medical research institute. These include hemophilia, thalassemia, sickle-cell anemia certain forms of muscular dystrophies, retinal dystrophies such as retinitis pigmentosa, corneal dystrophies, primary immunodeficiency (PID) in children, lysosomal storage disorders such as Pompe disease, Gaucher's disease, haemangioma, cystic fibrosis among others. Though it affects a small percentage of the population, the disease has vast, debilitating and life-threatening effects of the patients, many of whom are in the pediatric age group. “These national guidelines provide the general principles for developing gene therapy products (GTPs) for any human ailment and provides the framework for human clinical trials which must follow the established general principles of biomedical research for any human applications. The guidelines cover all areas of GTP production, pre-clinical testing, and clinical administration, as well as long term, follow up,” said (Prof) Dr Geeta Jotwani, a scientist at the ICMR.
ICMR issues guidelines for gene therapy in India
December 13, 2019/Outlook India

The apex health research body ICMR has released national guidelines regarding the procedures to be followed for developing and performing gene therapies to tackle inherited genetic or rare diseases in India. Gene therapy is a technique that uses genetic modifications to treat or prevent ailments. As a part of the procedure, clinicians treat a disorder by inserting a gene into the cells of patients instead of using drugs or performing surgery. "National Guidelines for Gene Therapy Product Development and Clinical Trials" document has been released to enable treatment of diseases by Gene Therapy, the Indian Council of Medical Research (ICMR) said in a statement. "The aim of the document is to ensure that gene therapies can be introduced in India and clinical trials for gene therapies can be performed in an ethical, scientific and safe manner," the ICMR said. Inherited genetic diseases or "rare diseases" (RDs) refer to medical conditions that affect a small percentage of the population but has vast, debilitating and often life-threatening effects of the patients, many of whom are in the pediatric age group, it said. Treatments for such diseases have long been neglected by the traditional pharma industry because of the notion that it will have uncertain or poor commercial outcomes given the smaller affected population size.

ICMR Issues Guidelines For Gene Therapy In India
December 13, 2019/Republic India

The apex health research body ICMR has released national guidelines regarding the procedures to be followed for developing and performing gene therapies to tackle inherited genetic or rare diseases in India. Gene therapy is a technique that uses genetic modifications to treat or prevent ailments. As a part of the procedure, clinicians treat a disorder by inserting a gene into the cells of patients instead of using drugs or performing surgery. "National Guidelines for Gene Therapy Product Development and Clinical Trials" document has been released to enable treatment of diseases by Gene Therapy," the Indian Council of Medical Research (ICMR) said in a statement. "The aim of the document is to ensure that gene therapies can be introduced in India and clinical trials for gene therapies can be performed in an ethical, scientific and safe manner," the ICMR said. Inherited genetic diseases or "rare diseases" (RDs) refer to medical conditions that affect a small percentage of the population but has vast, debilitating and often life-threatening effects of the patients, many of whom are in the pediatric age group, it said. Treatments for such diseases have long been neglected by the traditional pharma industry because of the notion that it will have uncertain or poor commercial outcomes given the smaller affected population size. Recognizing the huge burden of genetic diseases in India and therefore, the need to accelerate the development of advanced therapeutic options for such conditions, this seminal document will also serve as an important resource and roadmap for those in the field trying to develop gene and cell therapies, the statement said.
ICMR issues guidelines for gene therapy in India
December 13, 2019/Business Standard

The apex health research body ICMR has released national guidelines regarding the procedures to be followed for developing and performing gene therapies to tackle inherited genetic or rare diseases in India. Gene therapy is a technique that uses genetic modifications to treat or prevent ailments. As a part of the procedure, clinicians treat a disorder by inserting a gene into the cells of patients instead of using drugs or performing surgery. "National Guidelines for Gene Therapy Product Development and Clinical Trials" document has been released to enable treatment of diseases by Gene Therapy, the Indian Council of Medical Research (ICMR) said in a statement. "The aim of the document is to ensure that gene therapies can be introduced in India and clinical trials for gene therapies can be performed in an ethical, scientific and safe manner," the ICMR said. Inherited genetic diseases or "rare diseases" (RDs) refer to medical conditions that affect a small percentage of the population but has vast, debilitating and often life threatening effects of the patients, many of whom are in the paediatric age group, it said. Treatments for such diseases have long been neglected by the traditional pharma industry because of the notion that it will have uncertain or poor commercial outcomes given the smaller affected population size. Recognizing huge burden of genetic diseases in India and therefore, the need to accelerate the development of advanced therapeutic options for such conditions, this seminal document will also serve as an important resource and roadmap for those in the field trying to develop gene and cell therapies, the statement said.

ICMR issues guidelines for gene therapy in India
December 13, 2019/DT Next

Gene therapy is a technique that uses genetic modifications to treat or prevent ailments. As a part of the procedure, clinicians treat a disorder by inserting a gene into the cells of patients instead of using drugs or performing surgery. "National Guidelines for Gene Therapy Product Development and Clinical Trials" document has been released to enable treatment of diseases by Gene Therapy, the Indian Council of Medical Research (ICMR) said in a statement. "The aim of the document is to ensure that gene therapies can be introduced in India and clinical trials for gene therapies can be performed in an ethical, scientific and safe manner," the ICMR said. Inherited genetic diseases or "rare diseases" (RDs) refer to medical conditions that affect a small percentage of the population but has vast, debilitating and often life threatening effects of the patients, many of whom are in the paediatric age group, it said. Treatments for such diseases have long been neglected by the traditional pharma industry because of the notion that it will have uncertain or poor commercial outcomes given the smaller affected population size. Recognizing huge burden of genetic diseases in India and therefore, the need to accelerate the development of advanced therapeutic options for such conditions, this seminal document will also serve as an important resource and roadmap for those in the field trying to develop gene and cell therapies, the statement said.
ICMR releases draft guidelines to treat rare genetic diseases
December 13, 2019/ANI News

New Delhi [India], Dec 13, (ANI): The Indian Council of Medical Research (ICMR) on Friday released the draft guidelines for ensuring that rare genetic therapies and clinical trials can be performed in an ethical, scientific and safe manner in India.

“National guidelines for the treatment of patients suffering from rare genetic diseases” will assist medical experts to get genetic therapy product development and conduct clinical trials.
About 70 million Indians suffer from inherited genetic diseases or ‘rare diseases’ (RD), according to the apex medical research institute.
These include hemophilia, thalassemia, sickle-cell anemia certain forms of muscular dystrophies, retinal dystrophies such as retinitis pigmentosa, corneal dystrophies, primary immunodeficiency (PID) in children, lysosomal storage disorders such as Pompe disease, Gaucher’s disease, haemangioma, cystic fibrosis among others.
Though it affects a small percentage of the population, the disease has vast, debilitating and life-threatening effects of the patients, many of whom are in the pediatric age group.

ICMR sets up a task force on gene therapy research
December 14, 2019/The Hindu Business Line

Indian Council of Medical Research (ICMR) is setting up a task force on gene therapy research to encourage research in the emerging field. The research body among other things has proposed forming the task force to explore gene editing based therapeutic approaches to treat illnesses. In a call for research proposals, ICMR has stressed that many inherited disorders are not treated by current available drugs or traditional therapies.
Gene Therapy refers to the process of introduction, removal or change in content of an individual’s genetic material with the goal of treating the disease and a possibility of achieving long term cure.
While the western world has made considerable strides with regards to gene therapy over the past 30 years, ICMR stated that drugs like Luxuturna for Retinitis Pigmentosa, a condition which leads to breakdown of retinal cells in the eye, and leads to low vision, or Yescarta which is a cell therapy for cancer, are currently in clinical trial phase. ICMR has narrowed down on genetic diseases affecting the brain and muscles, eye disorders affecting the retina and cornea, heart diseases and blood disorders like Thalassemia, Sickle Cell Disease and Haemophilia. It has also stressed on diseases like Cancer, Diabetes and Lung diseases. “The strategies proposed should have a possibility of translation into future human trials,” the circular states.
ICMR releases gene therapy, clinical trials guidelines

December 14, 2019/Drug Today Medical Times

The aim of the guidelines is to ensure that gene therapies can be introduced in India and clinical trials for gene therapies can be performed in an ethical, scientific and safe manner, said an ICMR press statement. For a variety of debilitating diseases caused by genetic mutations, gene therapy offers a treatment modality that cannot be provided by conventional therapy, including small molecule drugs or alternative medicines, it said. “We hope this will spur innovation and accelerate research in rare diseases (RDs) in our nation. There remain many hurdles that the scientific and clinical community working in the RD fields has yet to overcome. Towards the goal of crossing these hurdles, the guidelines have been released to the nation,” said Dr Balram Bhargava, DG ICMR. Dr Bhargava said, “The government agencies recognise this problem and have been working with many groups around the country to establish rare disease policies as has been done in many western nations, to encourage the development of products intended to diagnose, manage or treat RDs as well as spread awareness and education to prevent inherited conditions.” In the past three years, several gene and cell therapy products have received approval for patient use from US and EU regulators, paving the way for development of therapies for a variety of previously untreatable disorders.

With regards,

Syed Adil Shamim Andrabi
Information Interface Officer/PRO
Indian Council of Medical Research-
Department of Health Research
Ministry of Health and Family Welfare
proicmr@gmail.com, syed.adil@icmr.gov.in
Ext. 286, Phone. 26589130