ACCEPTANCE OF MULTIREGIONAL CLINICAL TRIALS: **INDIAN PERSPECTIVE**

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The views captured in this paper are of individuals expressed in individual capacity and cannot be considered as views expressed in their official positions which they may be holding. Opinion expressed in this paper cannot be considered as legally binding and is expressed only for academic purposes.

Background: This white paper has been developed based on the opinion shared by academicians and subject matter experts in an advisory board meeting jointly organized by OPPI and ISCR with an objective to initiate discussions on acceptance of MRCTs data for new drug approvals in current scenario in India. This paper is solely academic in nature and cannot be constituted as an attempt driven with any commercial objective.

The paper gives a preview of advancements that are leading to changes in global regulatory space

Foreword:
India has 16% of the world's population but suffers from 20% of the world's disease burden, and the need of equitable access to innovative treatments and medicines will be one of the pillars towards universal healthcare.

In past few years we have witnessed regulatory reforms and pandemic has expedited the process. The Indian regulatory agencies were agile during the pandemic and this effort led to preventive and proactive actions, safeguarding patients. There is a need to sustain this momentum to improve access of state-of-the-art treatments for patients. Streamlining the regulatory framework by exploring scope for harmonization with other developed and developing geographies can address accelerated approval timelines for drugs and clinical trials leading to focus on innovation and fast-tracking newer therapies to reach the patients faster.

The objective of such harmonization is a more economical use of human, animal and material resources and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy and regulatory obligations to protect public health.
There remains a significant opportunity, for collaboration with international associations like International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) which have representations from regulatory agencies and industry will facilitate early access of innovative medicines to patients. Harmonisation can be achieved through the development of working principles based on ICH Guidelines via a process of scientific discussions and consensus with regulators, academia, and industry experts.
The whitepaper is a result of constructive dialogue on scientific issues amongst Indian regulatory authorities, academia, subject matter experts and the industry to facilitate the adoption of multiregional clinical research and drug development approaches and to potentially align current practices with that of international accepted principles.

The focus of the roundtable explored possibilities to improve access of newer therapeutics, technologies and diagnostics to Indian patient and evolving regulatory pathways, multi-regional clinical trials can address this challenge with promising outcomes. The paper gives a preview of advancements that are leading to changes in global regulatory space and serves as a conversation starter for all stakeholders to explore harmonization opportunities.

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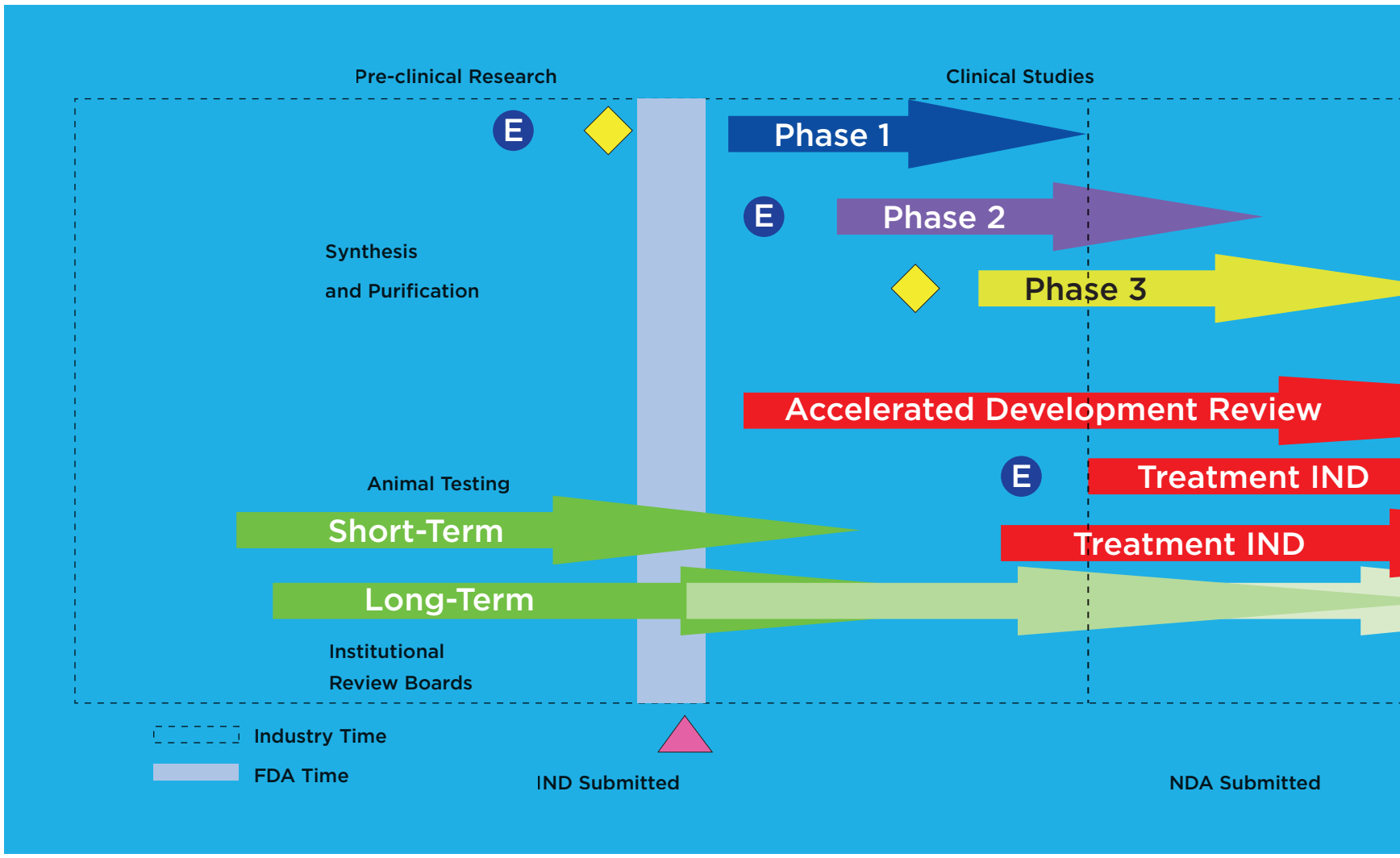

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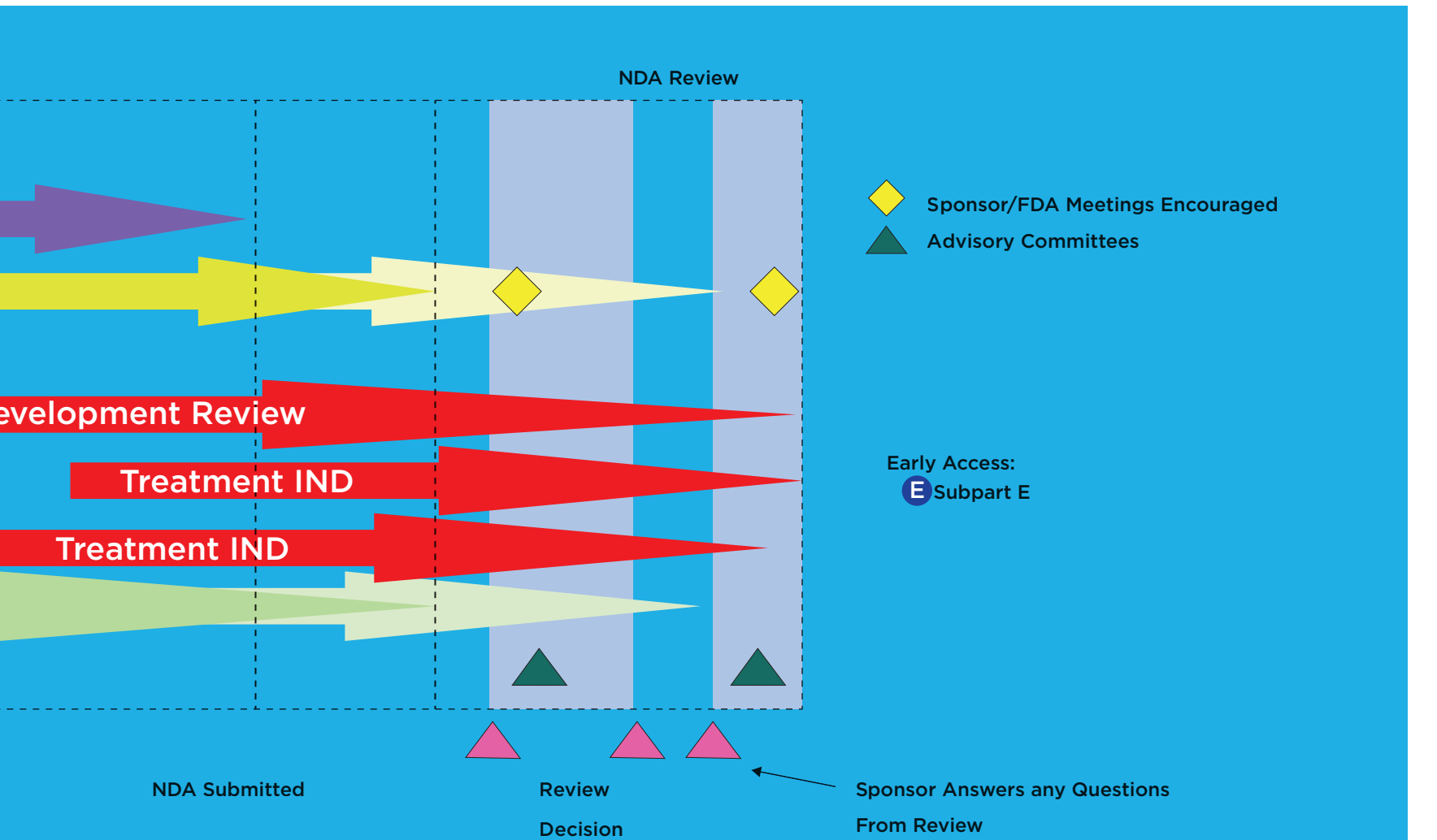
Nitika Garg, OPPI's Director of Research, Manish Paliwal, Director of Regulatory Affairs, Pfizer and Kedar Suvarnapatki, Director of Regulatory Affairs, Johnson & Johnson were the project's principal leads and were essential in developing this whitepaper. Nitika, Kedar, and Manish all contributed significantly to the study's success. We appreciate the OPPI team's assistance.

We would like to thank Dr. Sanish Davis, President of the Indian Society for Clinical Research (ISCR), for collaborating with OPPI on this multiregional clinical trial whitepaper (MRCT).



Preamble:

Over the last decade Indian drug regulatory environment has undergone substantial changes. The subject related suggestions by the joint parliamentary committee and guidance by Supreme Court of India has provided impetus to prepare correct legislative framework for conduct and monitoring of clinical trials in India. From 2013 to 2019, significant regulatory streamlining has happened at periodic intervals leading to the formation of New Drug and Clinical Trial Rules 2019 (NDCT 2019) which has given clear regulatory pathways and responsibilities for all stakeholders involved in the clinical trials. In NDCT 2019, there are provisions to rely on data generated in other countries if pharmacokinetics and pharmacodynamic similarities can be established without any anticipated safety concern in Indian patients. NDCT 2019 also has provisions for accelerated approval process and expedited review to handle pandemic situations. Since the fundamentals of multiregional randomized clinical trials (MRCTs) are also based on establishing similarity in anticipated clinical response in different population subgroups, existing provisions of NDCT 2019 should be sufficient for accepting MRCTs data, if scientifically justified. Deliberations are required while designing MRCTs for diseases which are specific to India or South Asian subcontinent for better regulatory decision making. The crucial consideration is to map the regional or country variability in terms of intrinsic or extrinsic factors which may impact the clinical data and regulatory assessment.

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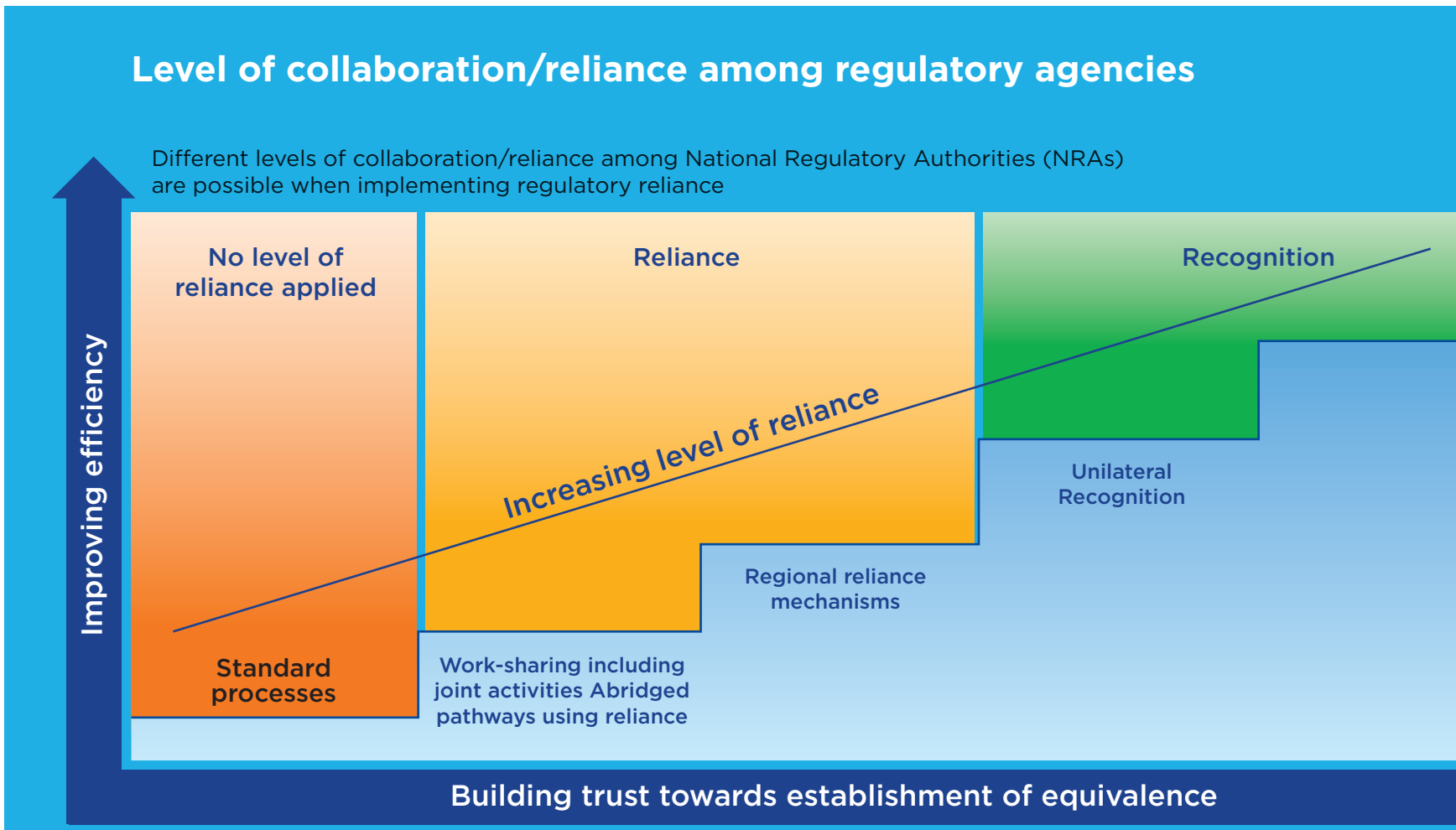
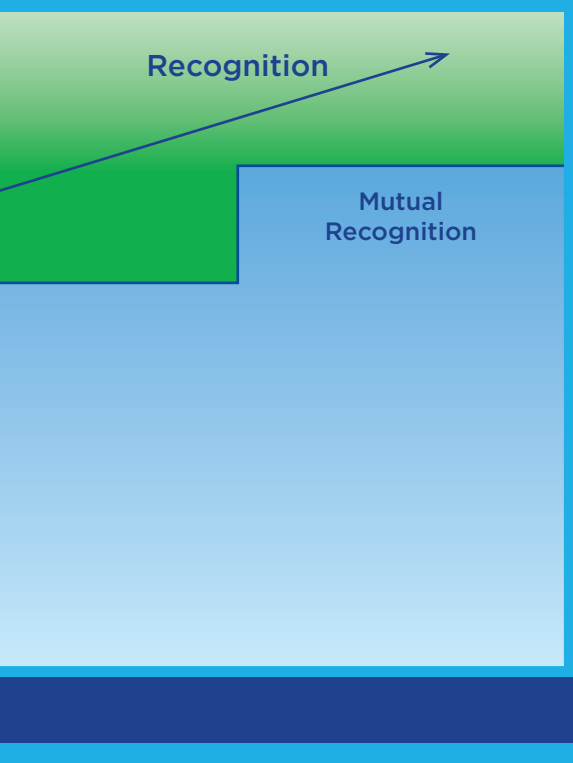


Fig 2. Above image is for illustration purposes only. Obtained from IFPMA Toolkit for supporting national-level capacities to advance regulatory reliance, May 2021

Quick learning attitude shown by regulator, industry, government, and academia has enabled the availability of many medicines for management of COVID 19 with quick turnaround time. Globally, there has been transformation in drug development to enable fast track launches and one such development is how do we rely on data generated in multiregional clinical trials without compromising on quality, safety, and compliance to the regulatory provisions. Most of the innovative drug molecules undergo a robust multi regional clinical trial process to include diverse set of patients which gives scientifically optimal data. If there is no variability anticipated in drug response or disease pathology, then multi regional clinical trial data may become a robust tool to enable simultaneous access of drugs without the need of undergoing local clinical trials which helps in rationalising cost, time, and resources. If India becomes an ICH member, this will enhance the potential of Indian healthcare industry by standardising processes and leveraging the data generated from other countries. This will also enable Indian companies to export their innovations to other countries much faster by mitigating the need of generating any additional data for export purposes since data generated will be based on ICH principles which are well accepted by many other countries. Global R&D environment has become more conservative in terms of less encouragement towards development of compounds which has pharmacokinetics or genomic variabilities across the countries. With the increasing shift in focus of global R&D from small molecule research to large molecule research and precision medicine, making ethnic variability considerations less important. Better understanding of disease, receptor targets and endpoints have led to linear, statistically justified pivotal clinical trials as main evidence to be relied upon for approving the drugs and the centre to all this is common principles of ICH leading to regulatory agility.

There is increasing reliance on data generated through MRCTs as these clinical trials are not just happening in developed nations but there is adequate representation of all regions, making



Reliance: Evaluations made by external regulatory authorities are considered in different degrees during the formulation of an individual assessment

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Recognition: No additional regulatory assessment is conducted. The decision is based on the evaluations made by an external regulatory authority

Independent decisions
Based on its own reviews and/ or inspections

Regional reliance mechanisms
Centralized evaluation conducted for a group of countries

Leveraging regulatory work
Performed by other competent and trusted authorities to reduce the workload, with independent final decision-making

Unilateral or mutual recognition
Based on treaties or equivalent, providing maximal benefits

Adapted from: World Health Organization (WHO), 2021. Good reliance practices in the regulation of medical products: high level principles and considerations. TRS 1033 (Annex 10)

these MRCTs a robust scientific tool for data generation. With increasing understanding and adaptation of ICH guidelines and regulatory agencies sharing knowledge and data is adding to environment of trust and regulatory reliance.

to benefit patients with early access. Many peer regulatory agencies like China and Korea are doing extensive engagement on topics linked to ICH E-17 guidelines to understand how ICH E-17 can make difference by enabling early access of medicines.

ICH E-17, multi-regional clinical trials – Objectives:

ICH E-17, multi-regional clinical trials guideline was first drafted in 2014 by ICH expert working group consisting of experts from industry, senior regulators from US FDA, PMDA, EMEA and with subsequent expansion of ICH members, regulators from South Korea, Taiwan, Singapore, Mexico, Brazil, and China joined the efforts and wrote ICH E-17 over the period of three years and final guidance was accepted in November 2017.

The overarching goal of ICH E-17 is to ensure simultaneous global development and near simultaneous registration of innovative medicines

7 Principles of Good MRCT Designs

(Simplified from the ICH E17 Step 4, Nov 2017)

01 Strategic use of MRCTS throughout drug development program

02 The intrinsic/extrinsic factors should be identified/ examined early

03 MRCTs are planned under the assumption that the treatment effect applies to the entire target population, where strategic allocation of the sample size to regions allows a proactive evaluation

04 Pre-specified pooling of regions or subpopulations may help provide flexibility in sample size allocation, facilitate the assessment of consistency, and support regulatory decision-making

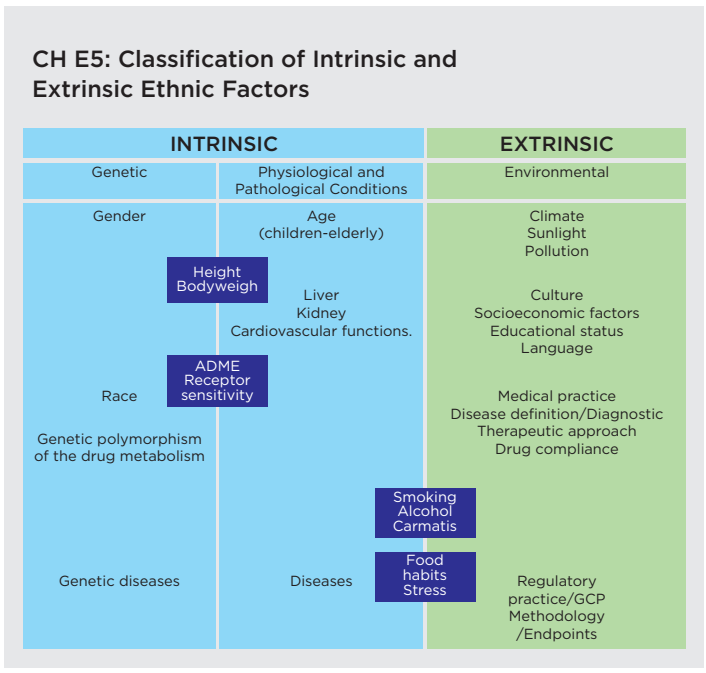
05 A single primary analysis approach should be planned so that it will be acceptable to all concerned regulatory authorities.
A structured exploration to examine the consistency of treatment effects across regions & subpopulations should be planned

06 Ensuring high quality of study design and conduct in all regions is of paramount importance

07 Efficient communication among sponsors and regulatory authorities is encouraged at the planning stage of MRCTs

Fig 3. Above images are for illustration purposes only. Obtained from site https://database.ich.org/sites/default/files/E17EWG_Step4_2017_1116.pdf - Accessed on 3 Jan 2022

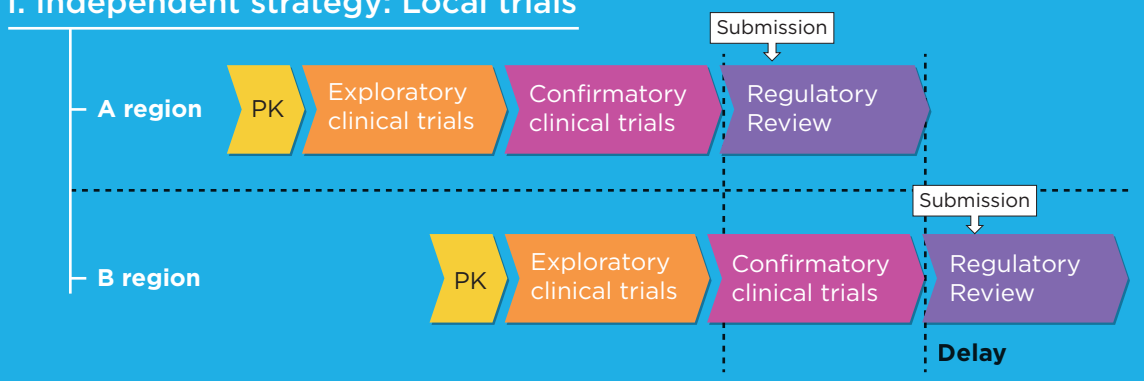
The basic objective of MRCTs is to accelerate the drug development process and shorten the approval time globally. If more socialistic and public health objectives of access and equity are included, then MRCTs become very much needed in the drug development to address unmet needs irrespective of countries involved in conduct of clinical trials. There are three important things one must consider while accepting MRCTs: (1) Knowledge (2) Attitude and (3) Training & Capacity building.



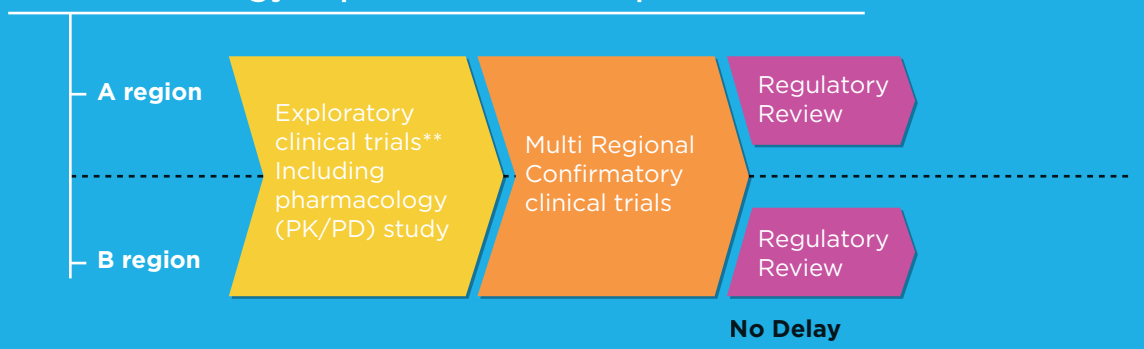
(1) Knowledge – Design of MRCTs should consider all the knowledge that is available – should include regional differences (ethnicity, health practice, polymorphism, etc.) that can change effect of drug and hence primary & secondary efficacy parameters to be taken into consideration while designing the clinical trials. All available knowledge about the country should be utilized to find out the possible regional or country difference on the intrinsic and extrinsic factors like local health practices. While defining primary objective in clinical trials, local variabilities should be incorporated in the trials like time to hospitalization, time to discharge which may vary significantly depending on the prevailing clinical practice in a particular country.

MRCTs and Global Drug Development

1. Independent strategy: Local trials



2. Global strategy: representative example of MRCTs



Source: ICH E17

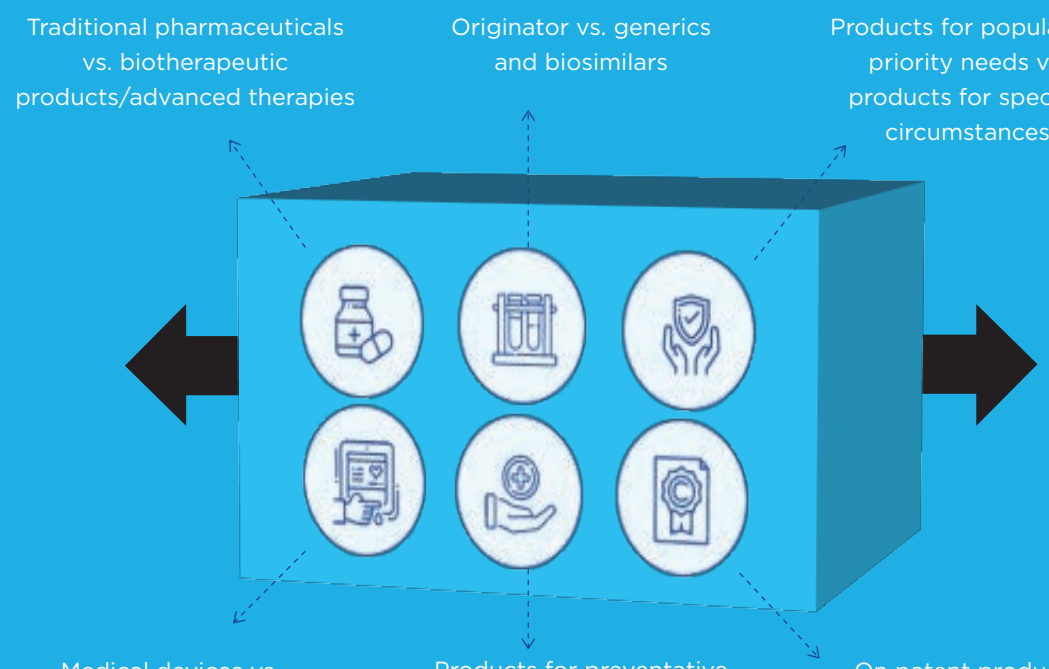
(2) Right Attitude – Industry, investigators and regulators should have correct attitude to design and approve such trial based on the understanding of country specific need and explore the possibilities of country specific protocol addendums to cover prevailing local practices to map all potential variations which may add to the scientific knowledge generation.

(3)Training & capacity building – MRCTs combine data from different regions so quality of data should be comparable. A lot of capacity building is needed at all the levels including regulators, investigators & ethics committees to map and understand regional differences and its impact on clinical outcome to take up multi regional protocols and its data for considering marketing approvals.

There is confidence in quality of data generated in ICH regions with MRCTs principles and the recent positive development is introduction of provisions in NDCT 2019 rules regarding criteria of waiver of local trials for the new drugs developed and approved in certain countries (the list of countries is yet to published). The regulatory environment is becoming more conducive with predictable timelines for CTA approvals which is a positive sign. To utilize the accelerated approval process more efficiently, there is need to define the drugs for which accelerated approval process should be considered e.g., reference could be USFDA guidelines. There is need to gain experience from the peer regulatory agencies in China and other countries on how they are approving the innovative pipelines, what are the key considerations for approval for new drugs and biologicals. Looking at the global scenario of MRCTs, countries like US, UK, Germany, France, and China has already implemented the guidelines and we should have knowledge exchange with these countries.

Medical products evaluated through regulatory reliance

Regulatory reliance can be used to assess different types of medical products[1]



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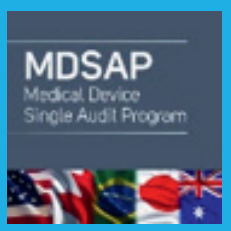
Drug Lag in India:

There was a study conducted by Thatte et al. to access the approval of new drug by US FDA, EMEA, PMDA and CDSCO India for the period of 2008 to 2017. The relative drug lag for CDSCO vis-à-vis, the USFDA, EMA and PMDA was 43.2 (2.1-1287.8), 25.6 (0.003-1310.5), and 30.3 (1.2-1242) months, respectively.

Total number of new drugs approved during the study period was 320 in USA, 275 in EU, 343 in Japan versus 86 in India. The drug lag has come down significantly over a period. The drug lag versus US was 78 months which came down to approximately 42 months, versus Japan drug lag was 75 months which came down to 25 months. There are some critical medicines where delayed access has been observed due to delay in approval in India like Bedaquiline for MDR-TB. There are also examples where India has approved drugs ahead of US FDA or European regulatory agencies. First approved drugs relative to other regulatory agencies, US FDA approved 249 drugs, EMA approved 110 drugs and PMDA approved 95 drugs and CDSCO has approved 59 drugs first relative to other regulatory agencies. There are few drugs which are approved in India ahead of other regulatory agencies like Saroglitazar, Itolizumab, Gemigliptin, Illaprazole etc. Along with drug lag, one of the key considerations is to evaluate the number of drugs which got withdrawn from India compared with other countries, which highlights the need of strengthening the pharmacovigilance system and ADR reporting. Kshirsagar et al. published a study regarding the timelines for withdrawal of drugs in India versus other countries covering the period of 1983 to 1998 and 1998 to 2012. One of the major findings of the study was that while drug approval timelines have improved in India, the timeline for drug withdrawal remained the same. This once again highlights the importance of development of robust pharmacovigilance system in the country. There is need to review the data on the new drugs approvals of past 3 years in India with that of peer regulatory agencies to see how India has done.

Example of applications of regulatory reliance to different medical products:



Medical devices: the Medical Device Single Audit Program (MDSAP)

WHO Prequalification Programme for Finished Pharmaceutical Products (WHO FPP PQ)

WHO Pilot Procedure for Prequalification of Biotherapeutic Products and Similar Biotherapeutic Products

Vaccines: the Solidarity Clinical Trial and the African Vaccine Regulatory Forum (AVAREF)

1. According to the WHO Good reliance practices in the regulation of medical products (Annex 10 in TRS 1033, 2021) particular consideration should be given to reliance approaches for medical products addressing unmet medical needs, public health emergencies or shortages and orphan and pediatric diseases

Acceptance of MRCTs in India - current scenario: India has 17% to 20% of global population and this reflects that we have very similar percentages of the world's morbidity in terms of disease. To get the patients in clinical trials to represent the entire spectrum of disease and to be a perfect fit to cover all possible variabilities maybe a utopian task, which is difficult to achieve. Hence a pragmatic solution can be to map possible variabilities to define fraction of patients to be included in clinical trials which may be representative of entire population. Most of global clinical trials are conducted in developed economies considering multiple factors and future profitability in mind. It becomes difficult for lower- and middle-income country (LMIC) regulators to determine what to look in the data to safeguard the population in their country. Therefore, it is mandated by regulation to go through certain processes leading to delays, multiregional clinical trials can address these points. However further deliberations are required on the framework to have adequate representation of Indian patients to support regulatory decision making in India.

One of the issues for acceptance of MRCTs data by regulatory agencies is "foreignness" of these drugs which may be both in terms of intrinsic factors like genotype and phenotype of patient or extrinsic factors like culture, access to medical services, regional treatment protocols or alternate therapies, etc. There is a need to have a roadmap to see how India can be part of early- stage global development programs or how to plan early stage bridging studies. Development of framework for accelerated development process and what could be categories of drugs which can be considered for accelerated process, especially the rare disease and orphan drugs in Indian context, should be a good start.

MRCTs talk about the global approach of drug development hence it is imperative to give due consideration to ethical aspects. The intrinsic and extrinsic factors, genetics etc. all should come into the picture at the designing stage of study for the various regions. However, it should be considered that India is a biodiversity rich country and there are always sub populations which, when used in research, outcomes can be extrapolated to other populations in developed regions. So, the choice of region should be such that there is an equitable distribution of burden and benefits i.e., the selection of regional sites is very important while designing the study.

Genetic variation and Drug Development:

Based on the population genomic data, there is variation in genotypes observed in India. While population genomics has relevance in drug development of precision medicine, clinical relevance of these genetic variations depends on which portion of gene structure the mutation has taken place. Mutation in the coding region of the gene may reflect variability in drug response whereas mutation in non-coding region may not be of any clinical significance. Genetic variability is more relevant if there are mutations in the specific enzymes or transporter involved in absorption, distribution, metabolism, and excretion of the drug. Effect modifiers should be considered in early phase of drug development preferably involving India, including dose range finding studies, as one of the participating countries. If there is variability involved, then adequate representation of that population is important in late phase studies in other cases extrapolation can be generalized among population. Use of pre-consultation process early in development of clinical study design to enable country specific inputs should also be encouraged.

Earlier the practice was to ask the applicant to do a bridging study in geographically distributed sites across India. However, since India has huge population and there is intra genetic heterogeneity, to find out any difference in terms of enzyme activation or gene or metabolism for any new drug would be challenging in controlled clinical setting. The correct picture in terms of difference would arise once the drug is introduced in real world setting and clinically meaningful assessment must be done from real world data to understand if there is any clinically significant difference in the drugs and population behavior. The potential variability in terms of any PK/PD parameters which can impact the safety, efficacy or dose for Indian subjects must be studied in the post marketing setting. In case, the products have been available in ICH regions for several years and there is adequate data as part of global development programs and the concern of potential difference in metabolism or regional variance has been addressed, and if there is no major safety concern, then decision can be taken based on the global data. During the pandemic few drugs have been approved in clinical trial mode without bridging studies, so this is another approach, i.e., if sufficient global data is available and there is emergency or unmet medical need, decisions can be made based on merit of global data with provision of active monitoring.

There are examples like Bedaquiline which has safety concern of cardiac arrythmia, and liver toxicity and it was used in restricted manner. A system of continuous monitoring has been developed in collaboration among various government agencies, this collaborative approach can help in the approval process and address the monitoring need specially for rare diseases and drugs.

Conclusion:

The need of hour is simplification of the New Drug Approval (NDA) process which should be logical and based on scientific principles. There is clear need to develop additional guidelines to cover the topics where there is lack of clarity and to make the existing guidelines much more efficient. Another key focus area is capacity building for better utilization of guidelines and principles. As part of drug development, efficacy is important; however, safety is an equally important parameter. There is need to have lots of dynamism, robustness and detailing of preclinical toxicology studies, clinical development, and post marketing authorization studies. MRCTs are a good idea to start with and this has to be a global effort. Theoretically MRCTs would be better option for data generation; however, this is not simple, and several factors must be considered for the success of MRCTs. If good outcome is needed from MRCTs, we need to take care of regional differences – scientific and general ones (technical expertise, attitude, resource, etc.). If these differences are considered, MRCTs can be a good approach. For any MRCTs to succeed in any country or region, regulatory environment must be supportive. The current environment in India is supportive of MRCTs. This is a perception from multiple case evaluation by CDSCO. Timeframe was a constraint in the past which is taken care of in current situation. For initial approval, MRCTs can be considered (to avoid delay) but if more variability is seen post approval e.g., dose modification etc. a country specific trial could be investigated post launch of drug and if any change is needed in approved label, it will benefit the surrounding countries as well going forward. Further discussions are required for framework on how to generate more local data and not always go through the traditional randomized clinical trials route to bring the data together. Patient registries could be supplemented to post marketing monitoring studies as in terms of real-world evidence for the post marketing surveillance. ICMR has several patient registries including oncology, diabetes, cardiac failure, stroke, and rare disease registry. Since there is already a huge data base available, this should be further utilized for data generation and assessment done. e.g., cohort studies for policy/regulatory decision making and resource optimization of already available information. Randomized clinical trials helps in establishing the efficacy but registries can be used as real-world evidence tool, to see the effectiveness, extrapolation, and study the variations as the RWEs will consider all the heterogenicity in terms of population, concomitant treatment etc. In all likelihood, utilizing the patient registries as RWEs tool for post marketing monitoring is win-win for all the stakeholders. This is supplemented by positive environment in India with launch of National Digital Health Mission which has a mandate of taking the electronic health registries and integration of data forward.

As a next step to these discussions, regulators can help coordinating for sensitization programs and leverage the global expertise like ICH trainers for knowledge transfer to various subject expert committee members as well as Ethics committee regarding the ICH E17 guidelines which will help in taking decision in a more pragmatic approach.

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