methods. This approach may demand a shift in research funding priorities, aligning them more closely with societal values.

The forum underscored both the achievements and limitations of the 3Rs principles, and we thank all the invited speakers for sharing their experience and knowledge on this topic. As technology and scientific methodologies evolve, replacing animals in experiments demands more than incremental improvements; it requires a paradigm shift that combines innovation, ethical responsibility, and cross-sector collaboration. The future of research and testing without animals may depend on how successfully we integrate these diverse perspectives and approaches.

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Meeting Report

Human Relevant Frontiers in Drug Safety and Efficacy

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Introduction

Indian regulations have been steadily promoting the adoption of alternatives to traditional animal-based non-clinical testing across various sectors, beginning with cosmetics and agrochemicals, and now expanding to drugs. This report covers a workshop organized by the Centre for Predictive Human Model Systems (CPHMS), the Central Drugs Standard Control Organization (CDSCO), and the Indian Council of Medical Research (ICMR) in July 2024, which explored emerging trends in complex *in vitro* models and computational modelling for drug development and discovery. The workshop urged key stakeholders, including regulators and funding agencies, to take an active role in advancing these new non-clinical approaches, to clearly articulate their expectations for academia, start-ups, and industry, and to engage in identifying priority frameworks for immediate collaborations.

In early 2023, India's Ministry of Health and Family Welfare (MoHFW) and the CDSCO reaffirmed their commitment to the 3Rs principle – replacing, reducing, and refining animal use – in regulatory assessments. They amended the New Drugs and Clinical Trials Rules (2019), allowing non-clinical testing methods for assessing the safety and efficacy of new drugs to include human-centric cell-based assays, organ-chips, microphysiological systems (MPS), sophisticated computer modeling, and other human biology-based methods, thereby reducing reliance on predominantly animal studies[1]. This is not, however, India's first step in this direction. The country's most notable advances in the 3Rs field came in 2014 when the Drugs and Cosmetics Rules (1945) were amended to prohibit the testing of cosmetics on animals[2]. This was followed by a ban on the import of cosmetics that have been tested on animals elsewhere[3]. In 2015, MoHFW and CDSCO ruled that drug companies no longer needed to repeat non-clinical toxicity tests on animals in India if a drug's safety profile had already been established in laboratories following Good Laboratory Practices (GLP) overseas[4]. In 2016, further progress was made by amending the Drugs and Cosmetics Rules (1945) to mandate that initial dermal and ocular toxicity studies of drugs must be conducted using non-animal alternative models in line with Organisation for Economic Co-operation and Development (OECD) guidelines[5]. In 2017, the Ministry of Agriculture encouraged an integrated testing approach to assess acute toxicity of pesticides endorsing *in vitro*, *in chemico*, *in silico*, and *ex vivo* non-clinical testing[6]. National Guidelines for Gene Therapy Products developed by the ICMR, Department of Biotechnology (DBT), and MoHFW in 2019 suggested that non-clinical evaluations could include *in vitro* disease models where specific *in vivo* disease models were unavailable[7], a decision that was extended to all drugs. These changes reflect India's ambition to shift toward non-clinical tests that are non-animal but also more predictive of human physi-

[1] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTk1Ng

[2] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTM3OA

[3] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTQ4MA

[4] Part XA: Import or Manufacture of New Drug for Clinical Trials or Marketing 122(A).(2) https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIwMjc

[5] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTU1OQ

[6] https://ppqs.gov.in/sites/default/files/toxguidancedocsept2017.pdf

[7] https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.pdf

ological responses. It aligns with the global regulatory movement, exemplified by the US FDA Modernization Act 2.0 signed in 2022. This act was the first to formally endorse human-based, non-clinical testing methods as viable alternatives to animal approaches for drug testing.

The recently proposed FDA Modernization Act 3.0 builds on its predecessor, emphasizing collaboration among diverse stakeholders, flexible regulatory pathways, and FDA's requirement to swiftly evaluate new test methods and report its findings to the Congress. This last point is particularly crucial and becomes even more valuable if the information is made publicly accessible. Transparent guidance on how these methods will be evaluated, a clear understanding of how these methods will be integrated into existing regulatory frameworks, and insights from both successful and unsuccessful regulatory dossiers are essential for the adoption of *in vitro*, *in silico*, and *in chemico* testing methods, reducing uncertainty of the process.

India boasts a thriving ecosystem[8] of academic and industrial stakeholders dedicated to developing human-relevant testing methods. In light of this and following the example of agencies such as the US FDA, the European Medicines Agency (EMA), and the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use, with whom India has strong ties, Indian agencies have the opportunity to evolve from being administrators to active participants, dedicated to driving meaningful outcomes in these areas. This can only be achieved through a continuous and nuanced understanding of the strengths, opportunities, and limitations of new non-clinical methods.

The Centre for Predictive Human Model Systems (CPHMS) is a science and policy think-tank established by the Atal Incubation Centre-Centre for Cellular and Molecular Biology (AIC-CCMB) and Humane Society International/India (HSI/India). Jointly with CDSCO and ICMR, the country's apex body for biomedical research, CPHMS organized an awareness and brainstorming workshop on *Human Relevant Frontiers in Drug Safety and Efficacy* on July 12, 2024, at the FDA Bhavan, New Delhi. The workshop aimed to update on the latest developments in novel non-clinical methods, with a focus on complex *in vitro* models (CIVM) and computational modeling and simulation (CM&S), and discuss strategies for advancing these areas in India, particularly involving regulators from the outset. It was attended by 50 stakeholders, largely regulators, along with subject experts (from academia, industry, and start-ups), key representatives from ICMR, the Biotechnology Industry Research Assistance Council (BIRAC), and HSI/India.

Workshop inauguration

The workshop was inaugurated by Dr **Madhusudhana Rao** (Chief Executive Officer, AIC-CCMB), who introduced breakthrough innovations taking place at AIC-CCMB and its one-of-a-kind program, CPHMS. He traced CPHMS' five-year journey in advocating for human-centric research in the country and emphasized how institutions like this bridge the gap between innovators and end-users, engaging with all stakeholders in the health ecosystem. This role extends beyond the reach of many research institutions. Dr **Rajeev Singh Raghuvanshi** (Drugs Controller General of India) underscored the importance of regular informal interactions between regulators, academics, and industrialists to better understand each sector's ongoing efforts, challenges, and strengths. He highlighted that in emerging fields like CIVM and CM&S, creating robust data is essential, a currently unmet need in India. Dr Raghuvanshi also underscored the need for agencies that could serve as end-to-end project managers in these fields. Dr **Nabendu Chatterjee** (Head-Discovery Research Division, ICMR) highlighted ICMR's commitment to alternatives to animal experimentation (Swaminathan et al., 2019) and the efforts of its institute, National Animal Research Facility for Biomedical Research, in establishing laboratories that support *in vitro* research into animal physiology. Dr **Surat Parvatam**, Senior Strategist HSI/India, described HSI's global research and toxicology program, which consists of a diverse team of experts collaborating with multiple partners to achieve a lasting change in the scientific and ethical landscape of biomedical, chemical, and biologics research.

Workshop lectures

MPS are advanced *in vitro* models that replicate the structure and function of human tissues and organs at a microscale level. Differing levels of design and biological complexity, as well as the presence or absence of fluid flow, have prevented a consensus on their definition. This has led to the introduction of the term complex *in vitro* models or CIVM (Jeong et al., 2019), which encompasses models of both low and high complexity. Recently, there has been a surge of work on CIVM and new approach methods validation (Marx et al., 2020; Baran et al., 2022), standardization[9] (Pamies et al., 2024; Reyes et al., 2024), qualification (Piergiovanni et al., 2024) and regulatory acceptance[10,11] (Turner et al., 2023). As a result of these discussions, roadmaps[12] (Hansell et al., 2024) have emerged for phasing out animal testing, particularly in the chemicals sector. It is now time to put these proposals into practice.

At the workshop, the inaugural lecture by Dr **Sujata Mohanty** (Professor, AIIMS Delhi) highlighted diseases like Parkinson's, diabetes, and cardiac conditions, which require cell or organ restoration and are not adequately treated by current drugs. These could potentially benefit from a stem cell approach. Her talk focused on 'Translational advances in stem cell biology' including regeneration, international and national guidelines, regulations concerning stem cell use as well as recent examples of approvals. Dr **Kasturi Mahadik** (Chief Manager, CPHMS) discussed the 'Adoption of CIVM by the pharmaceutical industry' based on three case stud-

8 https://aic.ccmb.res.in/mps-researchers-database/

9 https://www.cencenelec.eu/media/publication-july-2024-fg-ooc-roadmap.pdf

10 https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-guideline-principles-regulatory-acceptance-3rs-replacement-reduction-refinement-testing-approaches_en.pdf

11 https://ntp.niehs.nih.gov/whatwestudy/niceatm/resources-for-test-method-developers/submissions

12 https://data.europa.eu/doi/10.2873/34576

Tab. 1: Enhancing CIVM adoption in India by clarifying stakeholders' responsibilities

Stakeholder	Roles
Regulator: CDSCO	– Chairing amendment, standardization, validation and guideline discussions – Developing guidelines by engaging diverse stakeholders
Funding and research partners: ICMR, DBT, BIRAC, DST	– Identifying focus areas for CIVM and releasing call for proposals – Enabling academia-industry partnerships – Partnering with CDSCO to set up and fund CIVM validation centers – Knowledge partners at regulatory meetings
Standards associations: BIS, IPC, USP (India office)	– Engaging with diverse stakeholders to define standards based on health priorities and validations approved by CDSCO
Science & policy centers: CPHMS, HSI/India	– Improving CIVM awareness and adoption – Scientific capacitation among academia and industry – Nodal bodies liaising among diverse stakeholders from funding to regulatory assessments
Academia	– Contributing with scientific innovation (materials, devices, CIVM, etc.) – Engaging with industries for the creation of necessary assays and enabling knowledge transfer – Key partners in discussions on standardization and qualification processes
Large and small industries (pharmaceuticals, biotechnology, CROs)	– Incorporating CIVM in workflows and presenting robust data in validation meetings – Key partners in standardization, qualification, and validation processes – Recognition of CROs as accredited CIVM testing centers with investment from both public and private sectors

BIRAC, Biotechnology Industry Research Assistance Council; BIS, Bureau of Indian Standards; CDSCO, Central Drugs Standard Control Organisation; CPHMS, Centre for Predictive Human Model Systems; CRO, contract research organization; DBT, Department of Biotechnology; DST, Department of Science and Technology; HSI, Humane Society International; ICMR, Indian Council of Medical Research; IPC, Indian Pharmacopoeia Commission; USP, US Pharmacopoeia

ies: Merck & Co. (Gleeson et al., 2024; Zhang et al., 2024), Roche (Mitrofanova et al., 2024), and Johnson & Johnson-AstraZeneca (Jang et al., 2019). She emphasized the companies' crucial role in qualifying models developed by technology providers. Additionally, she alluded to studies by Inipharm[13] and Sanofi (Rumsey et al., 2022), where CIVM included in regulatory submission dossiers helped gain approval for human clinical trials. Dr **Viraj Mehta** (DMPK Scientist, Sai Life Sciences) spoke about the 'Crucial role of standardization and qualification guidelines in enabling the adoption of CIVM'. He stressed the need for consistent definitions, identification of priority areas, context of use (CoU), and a national validation framework. Dr Mehta also suggested distinct roles for stakeholders who would work together to improve CIVM uptake in India (Tab. 1).

Computational modeling and simulation (CM&S) are powerful tools that complement traditional evidence-gathering methods, including *in vitro* testing and animal or clinical studies. Over the last decade, CM&S has become a regulatory science priority at the US FDA, coinciding with the explosive growth in data science and model-based technologies. CM&S for generics is seen as the low-hanging fruit to promote increased adoption of global CM&S. The FDA's recent approval of generic diclofenac sodium topical gel (1%) marked the first time a virtual bioequivalence assessment using dermal physiologically based pharmacokinetic (PBPK) modeling supported a 'totality of evidence' bioequivalence approach (Tsakalozou et al., 2021). Guidelines on the application of CM&S for the use of generics are needed, similar to those released in 2023 on assessing the credibility of CM&S in medical device submissions[14].

Several of these points were highlighted by CM&S experts during the workshop. Dr **Bhairav Paleja** (Lead Scientist, Vantage Research) gave an 'Overview of computational modeling and simulation in drug development', explaining how these tools streamline drug development processes, saving time as well as costs, allowing for informed decisions on drug safety, efficacy, and dosing, and ensuring compliance with evolving regulatory expectations. He discussed two case studies that helped determine the first-in-human dose for a cancer vaccine without the need for preclinical studies and a bio-better that can allow for lower dosing frequency. InSilicoMinds, represented by **Nirnith Devireddy** (Founder and Chief Executive Officer) and Dr **Pranav Karmwar** (Chief Scientific Officer) discussed CM&S from a 'Regulatory compliance and approvals' perspective. They emphasized that *in silico* models could facilitate bioequivalence studies, dissolution safe space optimization, and biowaivers for generics, viewing these as key opportunities for early regulatory

13 https://inipharm.com/#our-science3

14 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions

acceptance. They stressed that these models not only reduce dependence on *in vivo* studies but also provide valuable predictive insight, which can be integrated into regulatory decision-making. A notable case study discussed the application of *in vitro-in vivo* correlation (IVIVC) in predicting the bioavailability of a modified-release formulation accepted by the FDA. The team also emphasized a significant regulatory achievement when PBPK modeling was successfully employed to predict drug absorption in patients with conditions such as hepatic impairment or altered gastric pH. Further strengthening their case, they referenced the FDA's Model Integrated Evidence (MIE) framework[15], which is designed to utilize integrated computational models to provide evidence supporting drug safety, efficacy, and quality. The FDA's MIE framework has been instrumental in establishing confidence in model-informed drug development, particularly in cases where traditional trial data may be limited or incomplete[16,17]. Dr **Tausif Ahmed** (Head of Biopharmaceutics and Bioequivalence, Dr Reddy's Laboratories) continued along these lines and presented his case for the 'Use of physiology-based pharmacokinetic modeling in clinical research'. Amid growing concerns about nitrosamine impurities, antioxidants and pH modifiers have been proposed as potential solutions. Using a case study, Dr Ahmed proposed that the effects of these excipients can be assessed using a combination of *in vitro* assays and physiologically based biopharmaceutics modeling (PBBM)[18]. Additionally, other use cases like the use of PBPK modeling for obtaining lower strength biowaivers, waiver of bioequivalence studies, and setting dissolution specifications were also discussed.

Brainstorming discussion

A brainstorming session was held to gather stakeholders' input on enhancing capacity building and technology development in CIVM, led by Dr **Kasinath Viswanathan** (Head of In Vitro Biology, Zydus Lifesciences) and CM&S led by Dr **Anita Krishnan** (Associate Vice President, Biocon Biologics). Participants of each group included assembled regulators, academics, industry end-users, technology developers, and funding agencies. Finally, an open discussion with all participants distilled key observations and take-home messages (Box 1).

Box 1: Key recommendations during the brainstorming discussion by the two groups

Complex *in vitro* models (CIVM)

Definitions of models under the broad CIVM category need to be clarified and standardized.

- *Focus organs:* Given their roles in detoxification and homeostasis, the liver and kidney should be prioritized as primary organs of interest.
- *Immediate applicability of CoU:* Emphasize CoU with immediate applicability, particularly in the areas of drug metabolism and pharmacokinetics, and disease efficacy. Given India's significant investment in biologics and biosimilars, CIVM should be explored as a valuable tool for assessing biosimilar variants and related impurities. These models offer enhanced prediction of safety risks, efficacy, pharmacokinetics/pharmacodynamics, and immunogenicity.
- *Reference compounds:* A panel of reference compounds should be identified to validate the proposed models.
- *Validation framework:* It is crucial to promptly identify and establish a validation framework. As CIVM models advance, adherence to GLP may soon become both desirable and essential.
- *Test guidelines for CIVM:* Create an overall test guideline framework for CIVM, akin to the framework developed for *in vitro* reconstructed human epidermis.
- *Fostering relationships:* It was noted that many innovative CIVM have been developed primarily for basic research, with limited focus on regulatory applications. Stronger dialogue and collaborations between technology developers and end-users are needed to ensure these models can be effectively adapted to meet regulatory requirements. Further, regulators may want to foster strong relationships with technology developers and end-users to build confidence in these models and generate more data.

Computational modeling and simulation (CM&S)

- *Case-by-case evaluation:* Indian regulators emphasized that submissions with CM&S data will be evaluated on a case-by-case basis, considering the CoU, validation status, and other relevant parameters.
- *Minimal guidelines:* Considering the availability of examples from international agencies, it is recommended that regulators release minimal CM&S guidelines for India. Defining acceptance criteria is critical.
- *Pre-submission mechanism:* Stakeholders should be informed about the existing mechanism to request a pre-submission meeting (controlled correspondence) with CDSCO focusing on generics dossiers with regulators.

Dr **Ramjee Pallela** (Chief Operating Officer, AIC-CCMB) summarized the consensus among all participants. Regulators emphasized the need for strategic, intensive training in CIVM and CM&S, a view shared by other stakeholders. It was suggested that academia-industry-regulator groups collaborate to draft guidance documents in these areas, which could then be adopted by regulators as official guidelines. Additionally, stakeholders proposed

15 https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/model-integrated-evidence-mie-industry-meeting-pilot-between-fda-and-generic-drug-applicants

16 https://www.fda.gov/drugs/development-resources/model-informed-drug-development-paired-meeting-program

17 https://www.fda.gov/media/163156/download

18 https://www.fda.gov/media/141720/download

establishing a funding mechanism, similar to that of the US FDA, to validate these new technologies and support their growth.

Conclusion

Dr **Sonia Gandhi** (Deputy General Manager and Head-Regulatory Affairs & Policy, DBT-BIRAC) presented 'DBT-BIRAC's initiatives in developing microphysiological systems (MPS) in India'. She highlighted that BIRAC, through its various initiatives, is promoting the development of innovative non-clinical testing methods. A special call was announced by BIRAC on establishing preclinical disease models (*in vitro* and *in vivo*) for drug discovery[19] in the areas of metabolic disorders, infectious diseases, oncology, and neurodegenerative disorders. A significant portion of applications received focused on *in vitro* models, including patient-derived immortalized cell lines, cell-based and high-throughput screening assays, organoid, organ-on-chip models, and high-throughput humanized 3D bioprinted models, as opposed to *in vivo* models like transgenic, knockout, and humanized animal models. She highlighted that a multidisciplinary approach including technology development support in the areas of material science, biomedical device engineering, stem cells, microfluidics, biotechnology, and quality is required to generate a strong pipeline of start-ups in this sector. Dr Gandhi also discussed the Regulatory Affairs and Policy division at BIRAC, which seeks to address current regulatory gaps in the fields of CIVM and CM&S, among others. The division focuses on standardization, CoU, and validation, working in collaboration with key stakeholders. Dr **Annam Visala** (Joint Drugs Controller, CDSCO) concluded the workshop with a vote of thanks to all attendees. She urged the participants to move forward in identifying partnerships for validation centers and emphasized the importance of maintaining strong industry participation in ongoing interactions such as these.

The workshop proved to be a useful and fruitful means for diverse stakeholders to discuss their ideas and views on CIVM and CM&S with Indian regulators and funding agencies. It highlighted the strong interest among all participants in systematically and strategically adopting these technologies, with robust science remaining a top priority throughout. A key takeaway was the readiness of the academic, industrial, start-up communities, and science and policy centers to contribute, but their efforts must be reinforced through initiatives, support, and incentives from the Government of India.

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Erratum to National Workshop on Alternatives to Higher Animals in Toxicology and Biomedical Science

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In this meeting report, which appeared in *ALTEX (2024), 41(3)*, 300-301. doi:10.14573/altex.2403151, there was an error in an author's name. The correct authors' list is:
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