Regional Consultation on Health Research Governance and Management in South-East Asia
7-10 November 2023, Delhi, India
Regional Consultation on Health Research Governance and Management in South-East Asia

7–10 November 2023, Delhi, India

Meeting report
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The views expressed in this publication are those of the author or of the participants in the Regional Consultation and not necessarily those of EDCTP, NIHR or the UK Department of Health and Social Care or of the World Health Organization’s Regional Office for South-East Asia.
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<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADVANCEID</td>
<td>An Asian Infectious Diseases Clinical Trials Network</td>
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<tr>
<td>BMRC</td>
<td>Bangladesh Medical Research Council</td>
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<tr>
<td>BRIN</td>
<td>Badan Riset dan Inovasi Nasional (Indonesia)</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control, Atlanta, USA</td>
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<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
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<td>CECHR</td>
<td>Central Ethics Committee on Human Research</td>
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<tr>
<td>CHNRI</td>
<td>Child Health and Nutrition Research Initiative</td>
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<tr>
<td>CHRD</td>
<td>Cabinet of Health Research and Development</td>
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<tr>
<td>CMC</td>
<td>Christian Medical College</td>
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<tr>
<td>COMPACTE</td>
<td>Combatting Bacterial Resistance in Europe</td>
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<tr>
<td>CTR</td>
<td>Clinical Trial Network Registry</td>
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<tr>
<td>CSTU</td>
<td>Clinical Studies and Trials Unit</td>
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<tr>
<td>DDG</td>
<td>Deputy Director-General</td>
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<td>DHR</td>
<td>Department of Health Research</td>
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<td>DMS</td>
<td>data management sharing</td>
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<td>DPRK</td>
<td>Democratic Republic of Korea</td>
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<tr>
<td>EARL</td>
<td>ethical, administrative, regulatory and logistical</td>
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<tr>
<td>e-EC system</td>
<td>Electronic ethics committee system</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>FAIR</td>
<td>findability, accessibility, interoperability and reusability</td>
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<td>FDA</td>
<td>Federal Drug Administration</td>
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<td>FERCAP</td>
<td>Forum for Ethical Review Committees in the Asian and Western Pacific Region</td>
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<td>FWA</td>
<td>federal-wide assurances</td>
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<td>GDPR</td>
<td>General Data Protection Regulation</td>
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<td>GCP</td>
<td>good clinical practice</td>
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<td>Acronym</td>
<td>Full Form</td>
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<td>GST</td>
<td>goods and services tax</td>
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<td>ICH</td>
<td>International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use</td>
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<td>ICMR</td>
<td>Indian Council of Medical Research</td>
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<td>ICTRP</td>
<td>International Clinical Trials Registry Platform</td>
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<td>IDDO</td>
<td>Infectious Diseases Data Observatory</td>
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<td>IECs</td>
<td>Institutional Ethics Committee</td>
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<td>INTENT</td>
<td>India Clinical Trial and Education Network</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>KII</td>
<td>key informant interviews</td>
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<td>LMIC</td>
<td>low- and middle-income countries</td>
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<td>MCM</td>
<td>medical countermeasures</td>
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<td>M&amp;E</td>
<td>monitoring and evaluation</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>MORU</td>
<td>Mahidol Oxford Tropical Medicine Research Unit</td>
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<td>MS</td>
<td>Member States</td>
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<td>NABH</td>
<td>National Accreditation Board for Hospitals &amp; Healthcare Providers</td>
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<td>NGO</td>
<td>non-governmental organization</td>
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<td>NIH</td>
<td>national institutes of health</td>
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<td>NHRC</td>
<td>Nepal Health Research Council</td>
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<tr>
<td>NHSSP</td>
<td>National Health Sector Strategic Plan</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>OUCRU</td>
<td>The Oxford University Clinical Research Unit</td>
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<tr>
<td>PREPARE</td>
<td>Platform for European Preparedness Against (Re-)emerging Epidemics</td>
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<td>RA</td>
<td>Regional Adviser</td>
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<td>R&amp;D</td>
<td>research and development</td>
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<td>REC</td>
<td>research ethics committees</td>
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<td>R&amp;I</td>
<td>research and innovation</td>
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<td>Abbreviation</td>
<td>Full Form</td>
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<td>SEAR</td>
<td>South-East Asia Region of WHO</td>
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<tr>
<td>SIDCER</td>
<td>Strategic Initiative for Developing Capacity in Ethical Review</td>
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<td>SOPs</td>
<td>standard operating procedures</td>
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<tr>
<td>TAG</td>
<td>Technical Advisory Group</td>
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<tr>
<td>THSTI</td>
<td>Translational Health Science and Technology Institute</td>
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<tr>
<td>UNDP</td>
<td>United Nations Development Programme</td>
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<tr>
<td>UNICEF</td>
<td>United Nations International Children's Emergency Fund</td>
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<tr>
<td>USA</td>
<td>United States of America</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WHO-CC</td>
<td>WHO collaborating centres</td>
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<td>WWARN</td>
<td>World-wide Antimalarial Resistance Network</td>
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Executive summary

The Regional Consultation on Health Research Governance and Management in South-East Asia was held in Delhi, India, on November 7–10 to provide strategic directions for governance and management of research for health in the WHO South-East Asia Region. The specific objectives of the consultation were to:

- review the organization structures, status and practices in governance and management of health research in Members States of WHO South-East Asia Region and recommend key actions to strengthen the national health research ecosystems in the Region;
- build consensus on key strategic areas that may be included as part of Regional Health Research Strategy (2023–2030); and
- consult on approaches to establish regional clinical research (including clinical trials) networks to improve coordination of multicountry research especially during outbreaks, pandemics and other health emergencies.

The meeting considered various topics pertaining to the governance and management of health research, including what constitutes essential research governance and management functions. In the first session, the participants discussed in three different groups, the importance of health research governance and management in improving accountability, effectiveness, transparency and quality in health research and considered the status of governance and management in their own countries and the Region.

Dr Jeremy Farrar, Chief Scientist, WHO, gave the keynote address outlining the role of WHO in improving the research ecosystems. A presentation from the National Institutes of Health of the United States of America (USA) demonstrated the NIH World RePORT System as a tool to monitor research investments and Indonesia presented utility of clinical trial registry as one of the research governance and management tools. Recommendations were developed on what constitutes essential research and governance functions.

The consultation then deep dived into three major functions. This was done through Group works and sharing specific experiences both from the region and from outside. All the Member States were divided into the 3 groups – Group 1 of large countries (India, Bangladesh and Indonesia), Group 2 of mid-sized countries (Nepal, Sri Lanka and Thailand) and Group 3 of smaller countries (Bhutan, Maldives and Timor-Leste):
a) Building effective, efficient, transparent and resilient national health research ethics review systems:

A background paper was shared with all participants outlining current situation in the region and potential actions that may be taken to improve the system. Presentation from Nepal and India provided examples of the use of online systems to manage submission and review process, value gained from developing national registration systems for Research Ethics Review Committees (NAITIK system) and experience of use of cloud-based platform that can be used by multiple research ethics review committees (e-EC system).

All participants convened in three groups to discuss various issues pertaining to ethics review system with particular focus on digital enablement of ethics review committees and convergence of other independent systems (e.g. clinical trial registries) into one single system to bring more transparency in the system and reduce burden on researchers. Recommendations were developed after the group work that may be taken up by the Member States.

b) Maximizing the full potential of public health research data to generate better health - Current policies and ways to improve the archiving of health research data and access to and use of research data.

The regional consultation discussed the potential for improved archiving of health research data and increased access to data for use by the wider research community to contribute to health research. Two of the key global research organizations and funders – NIH and the Wellcome Trust presented their data sharing policies and rationale behind them. In addition, Sri Lanka also presented its data sharing policies. All participants convened in three groups to discuss various issues pertaining to data-sharing. After discussing issues relating to improved data archiving and access in groups, recommendations were developed for follow-up work on data archiving and access.

c) Feasibility to establish regional clinical research networks; what, how and why

A background paper was shared with all participants outlining the vision and concept for establishing the South-East Asia Clinical Research Network.

Dr Timothy Jinks from Wellcome Trust presented the key issues and considerations while setting regional or multi-country research networks followed by sharing of experiences by Dr Hsu from Singapore National University in establishing one of such networks (ADVANCE-ID) in Asia for infectious disease and antimicrobial
resistance. Both the presentations highlighted the political and governance challenges, cross-border regulatory alignment, financial sustainability that need to be addressed while considering developing such networks. Finally, India presented its approach and progress made in establishing a national network – the Indian Clinical Trial and Education Network (INTENT); a multisite network within India. It is still in the early stages and research through the network is yet to take off.

The participants then discussed the desirability, feasibility and options to set-up such networks. All the three groups considered establishing such networks as feasible. Recommendations were developed based on outcome of group work.

d) Developing regional research governance and management strategy

A theory of change framework that underlies the proposed regional strategy for health research was shared with participants in advance and presented during the consultation on fourth day along with key building blocks. National experience on developing and using national research strategies was shared by Timor-Leste and Bangladesh. Participants then discussed regional strategy framework including how the progress may be monitored at regional level. The outputs from the group work were used to develop the recommendations.

Conclusions and recommendations: Based on the discussions during consultation and group work discussions, recommendations were developed in four key areas.

(a) Governance and management of health research: Seven essential health research governance and management functions that Member States must perform to ensure timely, quality, ethical and efficient health research were identified. Appropriate organization structures must be designated/created to discharge these essential governance functions along with allocation of sufficient human and financial resources.

(b) Building effective, transparent and resilient “fit for purpose” national health research ethics systems: This is an essential research governance and management function. Harmonization of ethical standards, review processes must be pursued by national health research governance bodies. Digital enablement of research ethics review systems should be pursued to improve transparency, accountability and efficiency as well as to facilitate harmonization of review processes. Efforts should be made to develop a single national electronic platform to be used by all the institutional ethics review committees, which will ensure harmonization of workflows as well as develop prospective research registries as one of the outputs of this system in place of the current standalone clinical trial registries required additional registration step by the researchers.
(c) Systematic archiving and increasing access to public health research data – Realizing the full potential of public health data to generate better health: Systematic archiving and sharing of research data should be recognized as an essential health research and governance with designation of appropriate organizations and resources and infrastructure to implement the same. It should also be part of national health research strategies. Greater access to and reuse of data should be promoted in an equitable, ethical and efficient manner. Member States should set realistic and achievable goals for policy and infrastructure development.

(d) Establishing a generic South-East Asian Regional Research Networks: As part of developing regional clinical trial infrastructure and readiness, all Member States and research stakeholder should formally recognize establishing and supporting publicly funded national (where feasible especially in large countries) and regional clinical research networks as important health research governance and management function based on its value in shared gains by Member States. Appropriate organizations may be designated as focal entities to develop such national networks and coordinate their participation in the regional networks. Appropriate governance and financing mechanisms should be co-created by all the stakeholders in consultation.

(e) Development of a regional research strategy: It was agreed to focus on research governance and management rather than on disease/condition specific work. It should build on agreed upon essential health research governance and functions and the draft will be circulated to all Members States for their inputs. The final strategy will be put forward for approval by the WHO Regional Committee for South-East Asia.
1. **Introduction**

The Regional Consultation on Health Research Governance and Management in South-East Asia was held in Delhi, India, on 7–10 November 2023.

1.1 **Objectives**

The general objective of the consultation was to provide strategic directions for governance and management of research for health in the WHO South-East Asia Region.

The specific objectives of the consultation were to:

1. review the organization structures, status and practices in governance and management of health research in Members States of the WHO South-East Asia Region and recommend key actions to strengthen the national health research ecosystems in the Region;
2. build consensus on key strategic areas that may be included as part of Regional Health Research Strategy (2024–2030); and
3. consult on approaches to establish regional clinical research (including clinical trials) networks to improve coordination of multicountry research especially during outbreaks, pandemics and other health emergencies.

1.2 **Participants and resource persons**

Excluding the WHO Regional Office for the South East Asia secretariat and consultant, there were 45 participants, including 30 participants from Ministries of Health (MOH) as well as national research institutes or national health research councils from nine Member States (Bhutan, Bangladesh, India, Indonesia, Maldives, Nepal, Sri Lanka, Thailand and Timor-Leste) and 15 special invitees and representatives of regional and global health research institutes (National Institute of Health (United States of America), National University of Singapore; Wellcome Trust, United Kingdom of Great Britain and Northern Ireland (UK), the Bill and Melinda Gates Foundation, National Institute of Health Research (UK), and the Drugs for Neglected Diseases Initiative (DNDi)). WHO staff from all the three levels of the Organization participated as part of the Secretariat. A list of participants and observers, and the secretariat is attached as Annex 1.
1.3 **Organization**

The Regional Consultation was convened by the Research and Innovation (R&I) Unit of the Department of Communicable Diseases (CDS) at the WHO Regional Office for South-East Asia. Dr Manju Rani, Regional Adviser (Research and Innovation) served as the responsible officer from the Secretariat.

Sessions were moderated by different country participants as well as representative of global research institutes. Different WHO staff members from different levels of organization acted as Rapporteurs for different sessions. The detailed agenda for the consultation is attached as Annex 2.

1.4 **Opening ceremony**

Dr Pem Namgyal, Director for Programme Management, welcomed the meeting participants and delivered opening remarks on behalf of Regional Director, Dr Poonam Khetrapal Singh.

While underscoring the critical importance of health research, Dr Poonam Singh questioned whether research is as effective and credible as it could be in producing the evidence needed to inform health policies and programmes. She reflected that while it was important that spending on health research should increase, it was equally important that research should be effective and of high quality to ensure best use of funds.

Better governance and management of health research offers the potential to achieve maximum returns on investment in health research in terms of improved health services and outcomes. It can do so by efficient monitoring of national research activity, identification of appropriate research priorities, prevention of duplication and utilization of research findings in the development of policies and guidelines.

Dr Poonam Singh expressed her hope that the Regional Consultation would examine issues relating to improved governance and management of research, better archiving and use of research data and ethical conduct in research, establishing regional clinical research networks and would produce practical recommendations that can be implemented by all the Member States in the near future.

The full text of Dr Poonam Singh’s message is attached as Annex 3.
2. Proceedings

2.1 Keynote address: Role of WHO in research and innovation
Speaker: Dr Jeremy Farrar, Chief Scientist, WHO HQ

Dr Farrar outlined the role of WHO in research and innovation and highlighted the need to ask strategic questions. How does a health research council in a country give research grants? Are these given in the strategic areas based on a country’s priority health needs or are these based on the researcher’s personal interest? He drew attention to the need for each country to aim for a robust, resilient and domestically supported research ecosystems.

He emphasized the need to ensure that research questions are relevant to the context where research is conducted instead of being driven by outside agenda, embedding health research into the health care and the need for community engagement. He also reiterated the benefits of research: every dollar spent on research brings back 9–10 dollars in terms of employment and economy.

2.2 Essential health research governance functions:
Day 1: Tuesday, 7 November 2023

2.2.1 The status of governance and management of research in the WHO South-East Asia Region – the key finding from National Health Research Assessment 2023 Presenter: Dr Anand Krishnan, Consultant, WHO-SEARO

In 2023, based on a recommendation of the SE Asia Regional Office’s Advisory Committee on Health Research, the Regional Office undertook a situational analysis of National Health Research System in seven Member States with special focus on research governance and use of evidence, which is still ongoing. The situation analysis was aimed at identifying the gaps in the current “health research ecosystem” and to inform development of Regional Strategy for Health Research (2024–2030).

Methodology: The assessment is based on virtual key informant interviews (KII) using a semi-structured open-ended tool in the seven Member States and a detailed desk review of available documents as sourced from websites of MOH, National Health Research Council (NHRC) or related sites, literature search (PUBMED, Google) and as provided by different respondents of Key Informant Interviews. A total of seven to 10 KII were carried out or planned in each of the Member States. The assessment was carried out in nine key domains (governance & NHRC, ethics oversight, research

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1 In 2020, the analysis had been done in Timor-Leste and Maldives, and hence these countries were excluded from this analysis. Democratic Republic of Korea and Myanmar were excluded from the current exercise.
prioritization, capacity-building, information systems, funding, research outcomes and use of research).

**Key findings:** The findings were presented based on desk review and KII completed as of now in nine Member States (excluding Myanmar and Democratic Republic of Korea (DPRK)), with the caveat that these may be updated later.

A nodal unit for research governance exists in all the Member States, though the organizational structures and functions of these nodal units vary greatly across the Member States, some reflecting the size of these countries. Eight out of nine Members States had a national health research council and in five of them the NHRC had a legal basis.

All the nine Member States had a regulatory framework for biomedical research. In some instances, there are multiple organizational structures with overlapping functions and roles affecting performance of this function and creating duplication and delays in research approvals.

While seven of nine Member States had a “Health Research Policy or Strategy”, the link to the action plan or monitoring of its implementation was not clear. Similarly, while six of the nine Member States have a publicly available prioritized research agenda, its impact on funding allocation and research portfolio was not evaluated by countries. Structures to ensure transparency and accountability in health research were few. While five countries reported having clinical trial registry, few are directly managed by national health governance structures and use of the data is suboptimal. Thailand is in the process of closing down its Clinical Trial Registry due to lack of funds.

**Ethics oversight:** Seven of the nine Member States have a national ethics oversight committee, and registration/regulation of Institutional Review Board (IRBs)/Research Ethics Committee (RECs) at the national level is practiced in three of the larger Member States, though it is not required in other three smaller Member States due to presence of only one or two committees.

**Ease of doing research:** Research is mainly occurring in universities with focus on quantity rather than quality motivated by career prospects. There is not much multi-disciplinary research and the capacity to draft good quality grant proposals is suboptimal. Access to research funding is cumbersome, inadequate, and fragmented. Limited access to research related resources and few incentives to engage in research were other concerns. Only few countries have provision for research allowance.
Reuse of data for research and research outputs: Few countries have appropriate policy and regulatory frameworks and platforms for data sharing (4/9). For some of the emerging areas such as genomic research, even fewer countries (2/9) have these guidelines.

As against the global average of 19.9 research publication per 100 000 population², the average number of publications per 100 000 population varied from 0.15 in Timor-Leste to 0.41 in India, 1.19 in Thailand, and 2.07 in Bangladesh. Substantial research wastage for various reasons including poor quality research, cost of publication, language proficiency may be possible reasons for suboptimal research outputs. Furthermore, research was not being translated into public goods with documentation and reporting being found to be lacking.

2.2.2 Group work 1: Improving governance and management of health research: What constitutes essential research and governance functions that must be performed at national level by appropriate designated organizations

All the Member States were divided into the three groups—Group 1 of large countries (India, Bangladesh and Indonesia), Group 2 of mid-sized countries (Nepal, Sri Lanka and Thailand) and Group 3 of smaller countries (Bhutan, Maldives and Timor-Leste). The group were given four questions to discuss, reflect and to report.

a) What do you think are the essential research governance and management functions that must be performed at national level by designated organization/institutions?

All the three groups considered research strategy development, research priority setting, coordination between the local research networks, coordination of IRBs, research funding for basic and clinical studies, digital platform for management, protection of one health, enhance ethical and scientific quality, enforcement GCP/ICH

The group with mid-sized countries listed regulation and ethical review, capacity (human resources), quality/standards, funding prioritization and infrastructure.

Sri Lanka mentioned Research management committee under MoH that meets monthly

The smaller-sized Member States mentioned research prioritization, research participant/subject protection, capacity-building/system strengthening, utilization of evidence, monitoring and evaluation, formulation and implementation of policies/regulations, collaboration

² https://data.worldbank.org/indicator/SP.POP.TOTAL
**b) Which of these functions are currently being performed? Reasons for non-performance for other functions.**

Most mentioned that there is no digital platform and lack capacity and human resources.

**c) What tools and options do national agencies have to perform each of these functions given the complexity of stakeholder and research landscape?**

None of the groups mentioned any digitally enabled tools or platforms to help them perform these functions expected out of them.

**d) Expectation of support from WHO**

Most Member States expected technical support, support for standardization of ethics committees, capacity-building and exchange/collaborative research.

## 2.3 Country experiences in tools and strategies for governance for health research.

### 2.3.1 Value addition and benefits from Clinical Trial registers: Presenter: Professor Indi, National Research and Innovation Agency (BRIN), Indonesia

**Clinical trial registries as tool for research governance:** Clinical trial registers have been proposed as a tool of research governance and management to improve transparency and accountability in health research especially clinical trials to avoid only selective reporting of clinical trials and to reduce duplication and redundancy in the clinical trials. Following the first clinical trial registry established by the USA, many more countries have established these registries, as of today 20 countries are providing data to the WHO International Clinical Trial Research Network (ICTRP). In the SE Asia Region, India, Indonesia, Nepal, Sri Lanka and Thailand have established clinical trial registries, out of which India, Sri Lanka and Thailand’s clinical trial registries are part of WHO-ICTRP.

**Clinical trial registry in Indonesia:** Indonesia established Clinical trial register (CTR) in 2012 through a MoH regulation supported by a MoH decree on conduct of clinical trials in hospitals and FDA regulation on procedure for approval of clinical trials. CTR is currently managed by Health Development Policy Agency (BKPK) of the Indonesian Ministry of Health (https://ina-registry.org). The CTR was established due to concerns around undisclosed clinical trial data and selective publication and to improve transparency by providing public access to ongoing and completed clinical trials, to prevent duplicative efforts and enhancing the quality of scientific evidence. By
providing a comprehensive view of clinical trial landscapes, it was also expected to improve patient safety by enabling better informed decisions by researchers, clinicians and participants.

Researchers, academia, health-care professionals and policymakers and funding organizations regularly use data from CTR. The data from CTR has been used to assess the trends in clinical trials. The number of clinical trials being conducted in Indonesia is steadily increasing over the last two decades.

However, several challenges have been encountered in maintaining the CTR including ensuring compliance with registration leading to incomplete registration, variability in data quality and data standardization, managing updates and amendments in the clinical trial post registration and improving data access and registration.

2.3.2 Tools to monitor research funding: World RePORT developed by NIH (USA) Presenter: Ms. Nandita Chopra, Office of Global Research, US National Institute of Allergy and Infectious diseases

Monitoring research funding across different research institutes and researcher over time may be critical to assess the overall research impact of the research funding. However, given the diversity of stakeholders, there are no ‘inclusive’ systems to track the research financing and it is not possible in most of the Member States in SE Asia Region to estimate the total health research investments.

A demonstration of World RePORT—an online atlas of health research investments currently used by 16 funders, first developed in 2013, was presented. The database helps to understand the research landscape, helps to identify the gaps and duplication in funding, makes local investigators more aware of the programmes supported in their institutions to build local networks and collaborations. WHO is using the data from World RePORT in the Global Observatory on Health R&D.

The platform is useful to a wide variety of institutions and stakeholders—funders, research organizations, development agencies and civil society. The system is not limited to just NIH (USA), but all types of organizations from different countries may participate. Data entered in the system includes 12 essential items including funding organization name, start/end dates, research organization name, investigator(s); and 10 additional data fields as available from partner organizations.

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Implications from SE Asia Region: Most Member States in the Region do not have any systems to track and monitor their research investments – one of the essential research governance functions. World RePORT provides a good example for doing so. Some large research organizations can either join World RePORT or develop similar systems in their countries.

2.4 Building effective, efficient, transparent and resilient National Health Research Ethics Review systems: feasibility and options.

Prospective ethics review of research proposals by independent Institutional research committees at either funding or implementing research institution has become an important component of research approval process, that is being increasingly criticized for being ineffective, duplicative, unharmonized across different institutions, causing substantial delays in research conduct. Hence it is important to look at the whole system, reflect how it should be reformed or reorganized which is fit for purpose.

2.4.1 Group work 2: Developing efficient, resilient and transparent national research ethics: Tools, options

Dr. Manju Rani, Regional Advisor (R&I) gave a brief background and guidance on the group work.

All the Member States were divided into the 3 groups—Group 1 of large countries (India, Bangladesh and Indonesia), Group 2 of mid-sized countries (Nepal, Sri Lanka and Thailand) and Group 3 of smaller countries (Bhutan, Maldives and Timor-Leste). The group were given seven question to discuss, reflect and to report.

1. Ethics review is an institutional responsibility; in this context what should be the role of national health governance bodies in guiding and monitoring REC/IRB? option, how and why?

All three groups agreed that national health governance bodies should provide the overarching policy guidance and set national standards that can be followed by institutional review committees operational in the country.

2. Digital enablement of RECs system: Use of online systems to manage the submissions and review process by ERCs – what is the desirability, feasibility, the current experience, options and sustainability of these systems?

All the three groups agreed on the value of these systems. As of now, very few RECs are using digital systems are managing the submission and review process. There is no national guidance on use of these systems and individual committees are trying to source these digital systems on their own.
3. Feasibility, desirability and potential value addition of registration of REC/IRB online in publicly accessible web-based platform maintained by national research governance bodies: experience, options (what models), how it will help in improving efficiency or resilience or transparency?

India, Bangladesh and Nepal are trying to register all the RECs/IRB operational in the country at the national level. Nepal and Bangladesh are doing it manually, India has an online system. However, two agencies are doing the registration of RECs at national level in India, leading to duplication and increased burden. However, impact of the national registration system on the overall efficiency and effectiveness of the review process is still not clear.

4. Feasibility of linking current stand-alone national research registries (CTR) with the REC review process?

It may be feasible but will require substantial national level leadership with development of national systems rather than an institutional level approach.

5. Feasibility, desirability and potential value addition of national/regional accreditation/certification systems for RECs.

The issues were raised about who should accredit, the cost of accreditation. The value addition or impact of accreditation on functioning of ERCs are also to be documented.

6. What other functions the RECs may be tasked with beyond just ethical review?

It was suggested that RECs may take on the tasks related to compliance with good research practices, data sharing and registration of the research in clinical registries.

7. Building capacity and improving performance of REC/IRB: Current status, Potential options and policies-

This issue could not be discussed in detail. However, many Member States requested support from WHO in this domain.

2.4.2. Country experiences

1. Nepal National Health Research Council Ethics Review online submission system: the experience, Presenter: Ms Namita Ghimire. Ethical review, monitoring and evaluation section, Ethical Review Board, Nepal Health Research Council (NHRC)

Nepal Health Research Council is an autonomous government body was established by an act of Parliament in 1991 to improve population health through evidence generation and policy recommendations.
NHRC has established an independent IRB, which was accredited by Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)/FERCAP in 2019 as well Federal Wide Assurances (FWA) from the office of Human Research Protection (USA). NHRC also published health research ethics training manual (2015), Standard operating procedure handbook for Ethics Review Board (2019), and National Ethical Guidelines for Health Research in Nepal in 2022.

More than 4000 research proposal were approved in Nepal by different IECs functional in the country between 1991 and 2023.

The NHRC’s IRB started using an online system to process its submission and review process since 2017. The system has separate logins for researchers and reviewers. The online submission process involves 8 steps:

Fig. 1. Workflow in online Ethics Review Committee System of Nepal Health Research Council

The system allows initial review, post-approval review, such as submission of interim progress report, proposal amendment request, submission of any adverse event, continuing review report (CRR), protocol deviation/violations, early terminations and final report.

The system also facilitates real-time tracking of proposals’ status, monitoring the research investment categorized in different ways (by disease, by research institution, etc.) as well as track the total revenue of the IRB.

The other advantages of the digital IRB system were pre-defined process fees, increased transparency, and easy access to document checklists and submission guidelines.

Some potential improvements may be supported for offline mode and integration with the mobile platform. The challenges include mobilizing funds to maintain and apply updates for online system, and staff turnover.
2. India’s National Ethics Review Committee’s registration system (NAITAIK): what is it? gain made and the way forward, Presenter: Dr Roli Mathur, Scientist, Indian Council of Medical Research (ICMR) Bioethics Unit, Director, WHO Collaborating Centre (CC) for strengthening ethics in Biomedical and health research

The national Research ethics governance framework in ICMR/Department of Health Research (DHR) in India comprises of National Ethics committee (ICMR-Central Ethics Committee on Human Research (CECHR), Institutional Ethics committees, Independent Ethics Committees, Common Ethics committees. All the ethics review committees are required to be registered both with Central Drugs Standard Control Organization (CDSCO) and Department of Health Research (DHR). National Accreditation board for hospitals and Healthcare Providers (NABH), accredits ethics committees functional in the country.

ICMR-Central Ethics Committee on Human Research was established in 1980 and is responsible for ethics quality assurance of high priority research and to set overall ethics policy and guidance at the national level.

The New Drugs and Clinical Trial Rules (2019) made use of ICMR guidelines mandatory for constituting Ethics Committee for biomedical and health research. These rules also required registration of Ethics Committees with the National Ethics Committee Registry (Naitik.gov.in) established by Department of Health Research in September 2019. It is a paperless registration system. As of November 2023, a total of 1654 registration applications from different type of ethics committees have been received, and 1265 provisional registration (for a maximum of two years) and 360 final certificates have been issued. While 42% of all registered committees (either provision or final) are at hospital/clinics, 24% are at medical college, interestingly 14% are independent ethics committees.

The registration on NAITIK portal requires, name, address, authority, profile and CVs of Chairperson & members, copies of SOP, change in EC composition, training certificates, change in applicant or head of institution, SOP update and audit details.

The key challenges include a lack of awareness among relevant stakeholders, no punitive provision in New Drug and Clinical Trial Rules to ensure compliance with rules and limited control over independent Ethics Committees. Other cause of concern is the duplication between two registration portals (Central Drugs Standard Control Organization’s Sugam Portal and DHR Naitik portal).
Discussion points: How the establishment of these registration portal has impacted the timeliness, quality or other aspect of research vis-à-vis the costs incurred to develop and manage the portal as well as costs on part of ECs to register? How different research stakeholders are using the data from these research portals?

Fig. 2. Ethics Committee Registration Process on Naitik platform of the Department of Health, India

3. India e-EC (Electronic Ethics Committee) system -gains made and the way forward, Presenters: Dr Nitya Wadhwa and Dr Neha Chawla, Translational Health Science and Technology Institute (THSTI)

e-EC or CReATE is a software suite of 5 novel IT tools, co-developed by Forum for Ethics Review Committees (FERCI) and PATH with a grant from BMGF in 2017.
e-EC is an online cloud-based platform\(^4\) that facilitates submission of ethics related application by researchers 24X7 anytime and from anywhere and their review and/approval by an institutional Ethics review committee. Multiple RECs operational in the country can register on the system and use it to manage their submission and review of research protocols. The system allows for an electronic, seamless and transparent process of application, while ensuring that the data remain confidential and secure.

The workflows in the system have been designed in accordance with the National Ethics Guidelines for Biomedical and Health research involving human participants (ICMR, 2017), the new Drug and Clinical Trial Rules (2019) and the FERCI Standard Operating Procedures for Ethics Committees. Though the system allows the institutions to use their own form (uploaded as pdfs), the institutions are encouraged to use ICMR common forms for ethics review to ensure harmonization of processes across different RECs functional in the country. Use of common forms and standardized templates (for letter of permission/approval and other decisions) also allows storage of data in a searchable database that can be used to facilitate future submissions.

The digital system saves significant time in tracking research proposal, offers increased data privacy, security and confidentiality, keeps external and internal

\(^4\) Currently hosted on MS Azure, servers located in India
communication at one place, and provides real-time transparent tracking of the project by all relevant stakeholders.

THSTI and Medical Research Council’s Clinical Trial Unit at University College London officially joined the working group in 2019, and now it is one of the core projects managed by Clinical Development Services Agency (CDSA), THSTI.

As of November 2023, there are 15 institutions (25 RECs) including government institutes, teaching organizations, an NGO and research organization are using e-EC on subscription basis (Rs 5000 + GST per month, 3 months of usage offered on trial basis to evaluate feasibility and usage). Before introduction of the subscription, 35 institutes were using the e-EC.

Some challenges are noted in promoting the system use including hesitancy to adopt a different system or method of review; limited human and financial resources to operate the system, additional requests from some institutions to sync the application to their local servers, reluctance of institution to share the operational costs (the number of institutes using the system has gone down by more than 50% after introduction of subscription, even though nominal).

2.5 Data sharing in public health research: rationale, issues and potential challenges, Presenter: Dr Manju Rani, Regional Adviser, Research and Innovation

Dr Manju summarized the status, experiences and policies across different countries and across different research organizations.

Few Member States have policy frameworks pertaining to data sharing and even fewer have set up platforms to facilitate this. Moreover, even where frameworks and platforms exist, implementation, enforcement and uptake have been low. Data sharing, where it is happening, is mostly at the behest of funding agencies who make it mandatory for their support for research projects. However, there is a growing global and international movement towards greater sharing of data in the context of public health research.

It was emphasized that data sharing can improve accountability, efficiency, quality and capacity in health research. It can also enable testing new hypotheses, reducing duplication, studying trends and informing policies. The presenter acknowledged that data sharing faces cultural, technical and infrastructural barriers. It also requires well-articulated policies, enforcement mechanisms and ethical safeguards.
The presentation concluded by suggesting some possible ways to promote data sharing, such as mandating data deposition, creating central data archiving repositories, prioritizing data with long-term and wider-value, and providing training programmes in all these aspects including data utilization and analysis. Participants provided their views on the broad contours presented including on the potential risks and challenges that could be encountered while developing and implementing. They agreed to delve deeper into these issues during the upcoming group discussions during the day.

2.5.1. Country experiences in data sharing: Sri Lanka, Presenter: Dr Samiddhi Samarakoon, Deputy Director-General (DDG), Ministry of Health, Sri Lanka

Sri Lanka has two national policies that promote and regulate data sharing in public health research: National Data Sharing Policy (Information Communication and Technology Agency 2013–2018) and the National Policy on Health Information (MoH, 2017). These policies aim to create an ecosystem where data sharing is encouraged, harnessed and delivered to the public and other stakeholders based on the principle of “right information at the right time”.

Fig. 4. Sri Lanka Data Sharing Policy Framework

![Sri Lanka Data Sharing Policy Framework](image)

The Policy outlines the service, data, technical, operational, change management and governance frameworks that support the implementation of the data sharing policies. These frameworks provide the classification, guidelines, regulations, agreements, mechanisms and processes for data sharing among different entities and sectors.
National Policy on Health Information 2017

The mission of this policy is to provide quality and timely health information for evidence-based decision making through establishment of a ubiquitous, integrated, resilient, dynamic, cost-effective and sustainable Health Information System.

In summary the policy has five main objectives: 1. To ensure 50% of all health institutions generate, disseminate and use timely and quality health information 2. To make available comprehensive systems for personalized and community-based health information management for shared and continuous care of care recipients 3. To ensure optimal data/information sharing and access to health information 4. To encourage suitable innovations related to health information management and eHealth in all information processes 5. To ensure security and integrity of all health data/information 6. To ensure sustainability of all health information systems.

While policy directive 3.3 mandates appropriate archiving of data, policy directive 3.4 specifically details that the sharing of data and information within and outside the health sector should be promoted.

Notwithstanding these two policies, access to the health data for different stakeholders remains limited and the policies are yet to be fully implemented.

2.5.2 Data sharing policies of research funders

1. National Institutes of Health (USA) Data Management: Approach and policy, Presenter: Dr Nandita Chopra, National Institute of Allergy and Infectious Diseases (NIAID), United States

NIH’s rationale for responsible sharing of scientific data that is generated using NIH funds is to advance rigorous and reproducible research (ensure validation of research results, making high-value datasets accessible, increase opportunities for citation and collaboration, and accelerate future research directions) as well as to promote public trust in research (foster transparency and accountability, maximize research participant’s contributions, stewardship over taxpayer funds, support appropriate protection of research participant’s data).

NIH Data Management and Sharing Policy (DMSP) has been developed through an iterative process involving community and other stakeholders’ engagement and feedback since 2016, with the policy finally coming into effect in 2023.

The policy expects that all scientific data and metadata generated from NIH-funded or conducted research will be shared with the research community in a timely and appropriate manner, unless there are legal, ethical or technical barriers. The policy
requires the data to be shared as soon as possible and not later than the time of an associated publication or the end of a performance period, whatever comes first.

To implement the policy, researchers are required to submit a Data Management and Sharing (DMS) plan when applying for funding. The plan should describe the types and amount of data to be generated, preserved and shared, the standards and metadata to be used, the repository and timeline for data sharing, the access and reuse considerations, and the oversight of data management and sharing. The plan will be subject to peer review and also assessed by NIH staff; and can be revised and updated throughout the award lifecycle. Importantly, the plan will be incorporated into the terms and conditions of the award and compliance to the plan will affect future funding decisions.

She emphasized the importance of the utilization of existing data repositories accessible to ensure data preservation. Finally, Dr Chopra drew attention to several references, educational material and online resources including sample DMS Plans to enhance the learning and understanding regarding this policy and its implementation.

2. Wellcome Trust: Polices for research data sharing, Presenter: Dr Timothy Jinks, Wellcome Trust, United Kingdom

The Wellcome Trust ensures that results from research funded by them is applied for the public good and endeavors to create a research environment that not only enables but also incentivizes researchers to maximize the value of their research outputs, including data, software and materials. Hence the Trust requires researchers to share data by making it publicly available or alternatively use intellectual property (IP) as a tool to help protect and commercialize an original idea, product or technology. This vision aligns with the present international consensus that puts emphasis on the need to share and preserve research datasets in a way that maximizes their long-term value. Examples of this are the UK concordat on open research data (2016).

Advantages of data sharing. Making data available in a timely and responsible manner ensures greater use of the data as it allows for other researchers to not only build on it and use it to advance knowledge and make health improvements but also to verify it. Sharing data enhances the transparency of the research process. Similarly, making software or materials such as antibodies or cell lines available to the research community supports reproducibility and can underpin further research. However, Wellcome trust is cognizant that in some circumstances, controls and limits on sharing are necessary to protect the confidentiality and privacy of research participants, or to enable IP to be developed, protected and used in line with our policy on intellectual property.
Guidelines underpinning Wellcome’s data sharing policy: Researchers are expected to maximize the availability of research data, software and materials with as few restrictions as possible. At publication research data as well as any original software that is required to view datasets or to replicate analyses should be publicly available. Data on public health emergencies must be shared as rapidly and widely as possible, and in advance of journal publication.

A data sharing plan must be included in the research proposal stage and will be reviewed as part of funding decisions. Wellcome Trust will fund justified costs for delivering the data sharing plan. In cases where data, software or materials that will hold value as a resource for others in academia or industry will be generated, applicants will need to include an outputs management plan. The data management plan must adhere to the FAIR (findable, accessible, interoperable and reusable) principles.

Researchers’ approach to outputs management is expected be dynamic and a reflective process. The shared outputs should be discoverable, use recognized community repositories for data and other outputs where these exist and use persistent identifiers for these outputs wherever possible. Finally, all users of research data, software and materials should cite the source, and to abide by the terms and conditions under which they were accessed.

Moreover, the presenter emphasized the need to share data with research participants. To this end, any successful interventions from Wellcome Trust’s funding must be made available to patients in the areas where the research was carried out and must be delivered through structures that already exist or are easily developed. In conclusion it was highlighted that researchers must comply with all relevant legislation relating to data, biological samples and ethics. Finally, the need for researchers to consider possible appropriate future uses for the data when they set up the study and design their consent processes to accommodate this.

3. Infectious Diseases Data Observatory (IDDO) - Creating a trustworthy environment for hosting, harmonizing and analyzing individual patient clinical data for infectious diseases, Presenter: Philippe Guerin, University of Oxford, UK

Developed in 2009, the Infectious Diseases Data Observatory (IDDO) is a scientifically independent, multidisciplinary coalition of the global infectious disease and emerging infections communities with a mission to accelerate the effective treatment and control of infectious diseases by strengthening research and the generation of evidence for policy through equitable data use. It provides the methods, governance and
infrastructure to translate data into evidence that improves outcomes for patients worldwide. Currently, IDDO has 16 areas of research with over 2000 global research contributors and hosts data from more than five million patient data.

The strategic pillars of IDDO include:

- **EQUITY** Delivers collaborative analyses addressing the priorities of disease-affected communities
- **SCIENCE** Brings diverse researchers and data sources together, integrating many different types of data
- **REPOSITORY** Holds the data within a robust, secure framework with independent oversight from global experts.

Why is data sharing necessary in the South-East Asia Region? There remains a dearth of information and research studies on infectious diseases affecting the low- and middle-income countries (LMICs) to guide policy development in these countries. Furthermore, most of the studies conducted in infectious diseases are heterogenous in their methodology, in their target population, in case definition and studying points as well as in the way data is reported. Hence even if hundreds of studies are conducted the data are scattered, the sample sizes are too small (compared to oncology and cardiovascular studies) and hence their comparability using standard aggregated meta-analysis is limited. Often researchers in LMICs don’t have the means to disseminate findings very rapidly. Giving real examples to substantiate his point, he emphasized that the evidence-base used to curate the guidelines on the Ebola virus was moderate to low data quality.

*The need for individual patient data:* The use of Individual patient data (IPD) may improve the scarcity and sparsity of data. To address this issue there are growing calls to conduct IPD meta-analyses, from not only WHO but also from many other global stakeholders. However, there is resistance to data sharing, and appropriate incentives to data sharing may increase the uptake of data sharing.

For example, a population-based study that explored ‘association between Influenza vaccination and risk of stroke in Alberta, Canada’ had public health potential, but due to the absence of documented consent of patients to share their data, data could not be shared according to the manuscript authors published in the Lancet. As a consequence, the study results could not be reproduced, which largely undermined the study’s transparency, while the reasons given for not sharing data do not appear to be very solid and could have been addressed by the authors prior to start the implementation of the study. This occurred despite Canada having Data Sharing
policies, revealing a disconnect between policy and practice. Furthermore, researchers during COVID experienced much difficulty in collating global data as data were scattered with no clear mechanisms and policies to access it.

*How does IDDO promote and implement data sharing?* IDDO is fully committed to FAIR (findability, accessibility, interoperability and reusability) principles and was the first to introduce DOI credit for data contributors, ensuring full academic credit through citations and metrics given to contributors. Data submissions and data access are managed through a robust contractual framework involving mutual understanding of how data will and will not be used. IDDO is compliant with the European Union General Data Protection Regulation (GDPR). IDDO data access requests are overseen by independent review groups, under the auspices of WHO.

The framework below illustrates how IDDO uses its platform to collate data. Individual patient data in various shapes and forms are obtained from the ministries of health, private sector and academic institutions. Following which data are cleaned and standardized, and then mapped into the IDDO repository, using the CDISC standard, (which is a standard used by the major stringent regulatory authorities). This process is underpinned by a security model and a legal analytical framework.

*Fig. 5. The Infectious Diseases Data Observatory (IDDO) Data Model*

To demonstrate the benefits of data sharing an example of IDDO’s first pooled data repository on malaria from the WorldWide Antimalarial Resistance Network (WWARN) was evidenced. Here the data sharing initiative assembled about 800 datasets, which is about 200 000 patient records in the repository and from this has arisen 80 publications which informed a series of changes in the WHO policy guidelines.
Implications for SEA Region: Many SEA Region Member States currently have no data sharing policies in place. There is need for Member States to emulate data sharing initiatives that are being endorsed globally.

2.5.3 Data-sharing: status, experience and policies: Group work

All the country participants were divided into 3 groups and were given the following topics to discuss:

1. Is it desirable to systematically archive and share the research data with adequate safeguards (privacy)—why? What value will it add?

Participants unanimously expressed the desirability of having mechanisms for systematic archiving and sharing of data in the context of health research. It was expressed that data sharing would enhance transparency and reproducibility, would maximize resources as open data reduces the duplication of data collection and analysis, thereby saving time, money and human resources. Moreover, open data sharing would further enable peer review thus acting as a quality assurance tool. Many more advantages of data sharing such as capacity-building, increase in public trust and allowing for a wider dissemination of results were discussed.

2. Setting up ‘data sharing’ policies, and platforms: feasibility? What challenges may be faced? What are the opportunities now to do the same?

Member States also reported that data sharing policies and platforms were feasible, but their feasibility depends on factors such as the type of data, research field, institutional support and available resources. Here are some considerations for establishing data sharing policies and platforms. Reported challenges of data sharing were issues around data quality, concerns on data confidentiality and data privacy, technology and logistics, intellectual property rights, perceived risk to national security, lack of legal framework, numerous agencies with their own policies and political interests, fears of misuse/misinterpretation of data.

Nonetheless the proposition of data sharing among Member States had some potential such as potential to enhance Member States research culture through possible collaborations, improve research networks, evidence-based policy, increased research publications, improved research surveillance system. Many countries have seen positive developments in data sharing, especially in fields like genomics and open-access research. Initiatives like the Human Genome Project have demonstrated the benefits of open data sharing for scientific progress and innovation.
3. Organizational responsibility developing these policies and platforms: Who/which agencies?

Identifying the driving forces behind the formulation of these policies and platforms was said to be crucial. Identified key players that can take the reins and guide this developmental process, i.e. government agencies: At the national or regional level, government agencies wield significant influence. They often spearhead the creation of data-sharing policies, especially in sectors involving public interest and funds. Health, environment and education agencies for instance, frequently contribute to setting standards and regulations for data sharing.

**Non-State Actors:** Independent entities outside the governmental sphere also play a pivotal role. Their involvement introduces diverse perspectives and approaches to the development of data-sharing policies.

**Academic and research institutions:** These institutions, at the forefront of knowledge creation, can take charge of formulating and implementing data-sharing policies for their researchers. Establishing dedicated offices or committees to oversee guidelines ensures effective development and enforcement.

**International/nongovernmental organizations (I/NGOs):** Non-profit organizations contribute significantly to shaping data-sharing practices. Their involvement extends the reach of policies and platforms to address global challenges and collaborations.

**Funding agencies:** Entities like WHO, WOAH, UNDP, UNICEF, IAEA, NIH and the European Commission hold sway over data-sharing policies. By making data sharing a prerequisite for funding, they actively shape the landscape and can allocate funds for the establishment of data-sharing infrastructure.

**Health-care institutions:** Institutions directly involved in healthcare provision can be key drivers, ensuring that data sharing aligns with the needs and priorities of the healthcare sector.

**Regulatory Bodies:** Bodies responsible for overseeing and regulating various sectors can contribute by establishing frameworks that facilitate responsible and secure data sharing.

**Professional Associations and Scientific Societies:** Organizations within specific research disciplines can set the tone for data sharing by establishing best practices, guidelines and codes of conduct. Their advocacy contributes to fostering responsible data-sharing practices within their respective fields.
These entities collectively form a dynamic network of leaders and influencers, each contributing to the comprehensive development of policies and platforms for effective data sharing. MS recognized the following gaps that will need to be addressed to promote data sharing: the need to develop overarching policy (respecting national and international policies), the need for a regulatory mechanisms and legal frameworks, establishing national archiving and data sharing platforms, the need to develop an action plan based on priority of the nation and identification and mobilization of resources.

4. Which should be scope of data and which data must be prioritized for systematic archiving and sharing?

All participants agreed that data with long-term scientific value must be prioritized.

5. What has the experience in your country with research data sharing as of now? Positive or negative.

None of the Member State reported any actual negative experiences, though many participants worried about the same.

6. What steps may be to carry this forward if it is desirable and feasible.

Participants discussed about developing the policy frameworks for data sharing as the first step.

7. Expectations from WHO to support this area of work?

The MS called upon The World Health Organization to mobilize financial and coordination support, to provide digital infrastructure capacity, to give guidance and best Practices, to facilitate capacity-building, provide advocacy and policy recommendations: facilitate collaboration and partnerships, monitoring efforts to ensure that data-sharing practices adhere to ethical and legal standards.

2.6 Regional Clinical Research networks-what, how, why

A background concept note prepared by SEARO was shared with all participants providing the vision on establishing a South-East Asian Clinical Research Network.

2.6.1. Regional Clinical Trial Networks: Key issues and considerations, Presenter: Dr Timothy Jinks, WELLCOME Trust.

Dr Jinks started with the need to take clinical research in the Global South from something done on people through research done through for people to research done with people. The current model of clinical research based on study-specific
infrastructure or multiplicity disease/condition specific single-use networks of 50–300 sites is inefficient from a both a time and cost perspective. There is heterogeneity in trial-site quality with loss of capacity and expertise built at high cost at trial completion. This individual-study and disease specific approach need to be replaced by sustained disease & intervention agnostic research networks.

The presentation articulated a vision for clinical trial networks in LMIC that improves, strengthens and stabilizes clinical trial capabilities which mitigates against inefficiencies in trial start-up phase and loses in skillsets after conclusion of studies. Such regional networks should be flexible, scalable and interoperable with other regional networks, build on existing capacity & enable participation in registrational studies.

Such regional clinical trial networks should be globally embedded, inclusive (hospital care & primary care, adults and children), providing a single point of access into a high quality, business oriented clinical research network that provides services to alleviate the Ethical, Administrative, Regulatory and Logistical (EARL) barriers to clinical research for faster start-up and reduced timelines and lower costs. Overtime, these networks will increase access to expertise on infectious diseases, enable regional/international cooperation and collaboration and will allow rapid clinical research response in the event of an emerging infectious disease or a pandemic threat.

Regional clinical trial networks will have benefits for sponsors (better coordination and standardization with single contact entry point, parallel follow-up, reduced costs), investigators (faster enrolment, ability to conduct multiple studies at the same time, reduced study start up time, support for administrative and operational activities, getting access to a platform for developing innovative trial designs) and for patients (faster access to medical countermeasures, lower cost of newer drugs due to reduced research costs).

To implement and establish such clinical trial networks, 19 key elements across six domains- network planning, trial design, site selection and start-up, study conduct, study close out & read out, and performance management must be considered. Dr Jinks provided a detailed description of the each of 19 elements. Critical path analysis of trials conducted through the network can identify operational challenges.
Fig. 6. *Key Elements to consider when establishing Regional Clinical Trial Networks*

Dr. Jinks then discussed the possible organizational structures to facilitate structural change and emphasized that network strategy needs to be *centralized* to ensure efficiency in financing, resource allocation and quality of trials across sites in the network. Similarly, trial pipeline management should be centralized to ensure a coordinated opportunity strategy across the sites. The central management team should also coordinate the regulatory engagement and market access considerations. Centrally developed standard operating procedures (SOPs) would increase efficiency and ensure quality standard of trial development across sites. Similarly, site contracting, site-feasibility assessment, data management should be managed centrally.

Notwithstanding the theoretical value for perpetual multinational clinical research network, there are several challenges in developing and sustaining such networks, such as cross-border regulatory alignment, funding and finance, governance structure and alignment of direction, underuse of network between studies. Notwithstanding these challenges, building regional clinical networks is necessary as shown by the world’s collective experience with COVID. It is also doable by overcoming implementation barriers and taking steps to ensure long-term sustainability of such networks.
2.6.2. Regional Experience of Regional Research Networks: Establishing an Asian Infectious Diseases Clinical Trials Network (‘ADVANCEID’), Presenter: Dr Li Yang Hsu, Singapore National University

ADVANCEID is a unique experiment in establishing international (primarily Asian) “warm-base” clinical trial network for infectious diseases to conduct high quality clinical trials that have global impact on management of infections. The vision for ADVANCEID is to become a “go-to” for evaluation of any new intervention, diagnostics or prevention strategies relevant to antimicrobial resistance and other infectious diseases.

The European Experience: Asia has highest shared of world’s population and can learn from Europe that has demonstrated excellence in organizing multi-country clinical research networks such as COMPACTE (combatting Bacterial Resistance in Europe) and PREPARE (the Platform for European Preparedness Against (Re-emerging Epidemics), which are now succeeded by ECRAID-BASE—a sustainable not-for-profit clinical research network. ECRAID provides an example of innovative approach of building “warm-base” networks that can rapidly adapt and respond to new emerging diseases, though it may be costly to maintain (unless continuous ongoing series of studies/trials).

Starting the ADVANCEID: Starting with initial discussions in August 2017 with Wellcome Trust (one of the main funders for the networks among Singapore MOH), it took almost five years to start the first study “Clinically Oriented Antimicrobial Resistance Surveillance Network- epidemiological survey” in March 2022. The network is managed by a full-time director and deputy director. The network now has 47 sites in 20 countries across Asia, out of which 29 sites are already recruiting for its first study, while contracts are still pending for 11 sites. Several clinical trials (RAPID, BIOVERSYS, PRACTical pilot trial design) are in pipeline that will implemented through ADVANCEID.

Team and governance: The current team of ADVANCEID includes 24 people including programme manager, project managers, data managers, administrative support staff and research staff. The network is housed in the National University of Singapore with an oversight committee comprising of Wellcome Trust, Singapore Institutions, Mahidol Oxford Tropical Medicine Research Unit (MORU), The Oxford University Clinical Research Unit (OUCRU) and Christian Medical College (CMC) Vellore. This illustrates the human resources that may be needed to run such networks.

Challenges in establishing ADVANCEID: Building on the challenges pointed by previous speak (Dr. Jinks) on political economy and cross-border regulatory challenges, establishing ADVANCEID also faced challenges form local (Singapore)
research (AMR not a local priority & prioritization of "innovative" research over large-scale clinical trials) and administrative policies (money cannot go overseas).

**The usual expected challenges:** The other usual expected challenges were varied research agreements and contracting procedures, ethics applications, procedures for research samples processing and analysis across countries and across sites within a country. Mobilizing commitment to data sharing, equity and inclusivity was another challenge.

**Anticipated challenges:** Financial sustainability (currently dependent on one primary funder-Wellcome Trust), risks from political instability, economic downturns and other disasters, sustaining engagement and trust within network partners and public & communities and potential competition from emerging/future regional clinical trial-networks are other anticipated challenges.

**Benefits of ADVANCEID for overall clinical trial ecosystem:** ADVANCEID investments in people through research mentoring for clinician researchers, training programmes in Good Clinical Practice, on-site mentoring and seminars is helping to build capacity. Capacity development is also reinforced through infrastructure development such as laboratory and sequencing capacity directly or indirectly by research grants.

**Conducting future studies on ADVANCEID:** Proposal of new studies can come from all network members and from pharmaceutical industry and the decisions will be taken by ADVANCEID leadership with strategic assessment/ scientific review and recommendations from International Scientific Advisory Board and Speciality Working Group.

To conclude, ADVANCEID provides a unique learning experience in Asia to set-up multi-country non-disease specific clinical trial networks.

**Discussion points:**

1. **Process of site selection in ADVANCEID:** Open call or 'refer' approach from former collaborators was followed, though efforts were made for strategic site selection in some countries. However, overall, the section process is not very democratic and is based on interests and through acquaintances.

2. **How can research sites used in COVID join ADVANCEID and what funding opportunities are available?** The COVID sites can join the network for specific studies based on thematic areas; The network is engaged in capacity/capability development at sites rather than providing funding.
(3) Sustainability: Network should not be exclusive. The network partners can do other research activities.

(4) Private use of network- Market access: big countries use networks for market access to products than small countries. Engagement with the private sector is beneficial as it unfolds funding opportunities.

(5) Consultation with ministry or regulatory authorities on data sharing when adding sites to the networks? ADVANCEID makes direct access to clinical sites in many countries and in some countries via ministry and regulations/polices, data- as per local regulations in each country. While setting up databases in countries, transparency and accountability is ensured.

2.6.3. National Experience: Indian Clinical Trial and Education Network (INTENT): Presenter: Dr Taruna Madan, Scientist, Clinical Studies and Trials Unit (CSTU) ICMR

CSTU established on 14 September 2021, is in the early stages of establishing INTENT—currently still at the stage of ideation and SOP development.

Vision, mission & objectives of INTENT: Generation of high-quality evidence of global standards on national public health priorities by conducting hospital- and community-based trials to inform health policies and management practices. INTENT should also contribute to capacity-building of clinical researchers in India.

The rationale for developing such a not-for-profit network is to ensure better representation of diverse Indian community, inclusive of all levels of health care, reduced timelines for study completion.

Steps in establishing INTENT: Following the technical approval of INTENT, Regional Clinical Trial units and Advance Centres for Clinical Trials will be selected. A call for proposals will be made followed by administrative and regulatory preparations along with capacity-building through online training.

Governance structure for INTENT: INTENT will be governed through a Central Coordinating Unit at CSTU in ICMR, supported by Technical Advisory Group (TAG), Project Selection Committee, Data Safety and Monitoring Board and Data Management Committee. The Central Coordinating Unit will do all the preparatory activities (e.g., maintaining a website, floating expression of interest for sites, call for proposals for research studies, developing electronic data capture platforms) as well as undertake capacity building and monitoring activities.
Instead of using a “Hub and Spoke model” for INTENT, a level-field for clinical trials is proposed with no separate provision for human resources at each center/site in the network and only seed funds will be provided for preparatory activities. CSTU will be staffed with permanent technical officers and will hire other contractual human resources for trial support services.

**Selection of research sites for INTENT:** An independent five-member Screening Committee will do site selection based some selection criteria (same for both government and private sector sites) and quantitative and qualitative assessments and ensuring regional representativeness (North, South, East, West, North-east, central). The sites in the Network will include 12 Advanced Centers for Clinical Trials (institutes, medical colleges, hospitals with expertise and experience in randomized control trials) and six regional clinical trial units (model rural health research units, multidisciplinary research units) and 20 ICMR centres for clinical trials.

**Research projects through INTENT:** The network will prioritize ‘academic’ trials, though but ‘regulatory trials’ that address national public health priorities will also be allowed. Any network member can apply to conduct studies on INTENT and the research application will be technically evaluated and recommended by the Project Review Committees. For each trial, expression of interest will be invited from all sites within the network. Research questions will be prioritized in consultation with all the stakeholders following acceptable methodologies (e.g., Child Health and Nutrition Research Initiative (CHNRI) methodology).

**Capacity-building under INTENT:** One of the core objectives of INTENT is capacity-building and it will follow five steps—step 1 involving one-week training workshop on concepts and theories of clinical trials design and conduct, step 2 – submission of concepts proposals by trainees, step 3 – one week training workshop on advanced operational aspects of clinical trials, step 4 – mentorship programme for development of full proposal and implementation and step 5 – assessment of outcomes.

**Status of Network as of November 2023:** As of now, brainstorming meetings have been organized to finalize the framework of INTENT with financial approval pending. Identification and selection of participating institutions have been done following invitation of Expressions of interests. Initial brainstorming meeting have been held with Advanced Centers for Clinical Trials and Regional Clinical Trial Units and knowledge partners along with competency mapping. However, specific research projects are yet to be initiated though the Network.
In the next five years, the Network will consolidate Advanced Centers for Clinical Trials and Regional Clinical Trial Units and undertake several randomized clinical trials with publication of the new evidence in peer-reviewed journals and translating the evidence into change in clinical management/policy guidelines at local state and national level.

**Discussion:**

*How does INTENT support Regional Centres?* Support is provided through standard operating procedures on how to conduct randomized clinical trials, training programmes and by providing funding from the Department of Health Research.

*Interoperability for international collaboration:* TAG advised collaboration with international and local networks. Partnership with WHO and neighbor countries will also be explored.

*What lesson learnt from Journey of the Network so far:* Securing funding and consultative framework building is must, and it may take a lot of time.

*Support on capacity-building for other countries:* INTENT, guided by the role India is playing globally in the context of G20, is streamlining engagement process in the international arena and making capacity-building opportunities available in the Region.

*How can we get the network effect/synergies from INTENT:* The central mechanism, central ethic committees and two-way communication between center and local bodies, review of regulations and understanding the pain points and factors that hinder or facilitate research. Guidance will be developed on how to take ethics approval for multi-centre trials, how to hold joint ethic committees for multi-centre trials.

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**2.6.4 Group work: Desirability, feasibility, options for establishing regional clinical research networks? Key discussion points:**

Different grouping was used mixing big and small countries for this groupwork (group 1 – Bhutan, Thailand and India; group 2 – Indonesia, Nepal and Timor-Leste and group 3 – Bangladesh, Maldives. And following questions were given for group reflection:

**1. Is it desirable to set up multi-country research networks? What value will it add?**

All the three groups considered setting up such networks desirable with value addition from collaborative knowledge sharing, inclusion of diverse patients and populations, ensuring timelines of research, better funding opportunities, ability to do low-incidence diseases, allowing participation of small countries in the clinical trial, enhanced
research quality, leveraging specialized skills and resources, better prospective of capacity building

2. Is it feasible to set up such networks—What legal, operational and financial issues must be addressed

With the cooperation of all Member States, it is feasible to set up multi-country research networks. The key logistical issues may include ensuring administrative support, data privacy, different regulatory policies and capacity across borders, need for protocol adjustment relevant to local context, socio-political-cultural sensitivities, issues around benefit sharing and intellectual property rights.

The feasibility may be enhanced by focusing on developing partnerships, ensuring political commitment from all the Member States, effective planning, management, and monitoring and utilizing technology right from the beginning.

A financial sustainability plan needs to be developed right from the beginning. Different fund mobilization strategies such as grants, regular budgets in each country, membership fees, in-kind contribution, resource-sharing and sponsorship endorsement may be employed.

3. What may be different options to build such regional research networks. Which organization in Member States should be responsible for initiating and maintaining them? Where should be the secretariat?

A steering committee with participation from all Member States with national research council in each Member State serving as the focal point. The secretariat for the network may be rotated across Member States.

Building such network should explore government and policy support, academic collaborations, government, partnership with key international research organization.

4. What should be the scope (in terms of type of research) of these networks and how these should be funded?

The network should not only allow for clinical trials for epidemiological studies but also for, inter-disciplinary health system and policy and operational research. Research on traditional medicine, which is common in most of the Member States in the Region, should be incorporated. Wide and representative geographic coverage is essential.
5. How these networks may be governed and managed? What WHO may do to support this process

A governance structure, if possible, with rotating secretariat and signing of Memorandum of Understanding. Subgroups or subcommittees may be established for different themes. WHO should engage/broker to ensure transparency and accountability in resource allocation and funding, benefit sharing and developing clear mandate and objectives of the network. WHO can also play a role by providing technical and financial support, building capacity and appropriate communication.

Discussion:

What is needed to advocate to initiate South-east Clinical Research Network in countries in South-East Asia Region:

National health research councils and research units in MOH may do advocacy within the countries.

Operational navigation: 1. Seeking Regional stakeholders opinion, 2. Countries with policies to share with other countries to study and adapt; 3. Conduct dialogue between stakeholders, 4. Involvement of different stakeholders – For example in Sri Lanka, national health development committee multiple stakeholders including donors, other ministries etc. – such a body could easily be the appropriate forum, needed for conducting advocacy in local setting.

Maldives: to advance the agenda, the country needs a national policy for being in the regional networks, also needed is to establish a section for being responsible for the activity in the MOH.

2.7 Regional Research Strategy

2.7.1 Key building blocks of Regional Strategy, Presenter: Dr. Anand Krishnan

The proposed regional strategy for health research will articulate the key strategic priority areas and specific actions under each of them guided by a vision, mission and a conceptual framework. It will be aligned with other global, regional and national strategies and public health mandates and will incorporate learnings from COVID-19 epidemic and from previous two regional strategies (2012–2016 and 2018–2022). It will be based on key guiding principles of quality, efficiency, inclusiveness, resilience, transparency and accountability. In addition, it will provide guidance on the implementation as well as a monitoring framework.
The Regional research strategy is needed as the need for high quality research-based evidence continues amidst increasing complexity to do the research, increasing costs and risks. To mobilize additional resources for health research, efforts are needed to show returns on research investments and to ensure utilization of research outputs.

Some of the strategic priorities in the strategy will be 1) recognition of essential research governance functions and investing in them 2) identifying priorities and steering research investments to those priorities 3) establishing effective and resilient digitally enabled national ethics review systems 4) setting up national and regional research networks 5) sharing of public health research data, 6) developing systems to track research landscape and investments, preferably as a byproduct of research approval systems.

The implementation framework will specify the implementation agency, relevant stakeholders, and clear role of Member States and WHO. The regional strategy will also have a monitoring and evaluation framework with definition of inputs (policies, laws, guidelines, infrastructure, training), process (ease of doing research, financing, transparency, safety), outcomes (quantity and quality of research) and impact (improvement of population health linked to specific research outcomes) and indicators will be defined for each level of monitoring framework.

2.7.2 National Health Research Strategy (2023–2028): Timor-Leste, Presenter: Dr Marcelo Amaral Mali and Dr Noel Gama Soares

The National Health Research Strategy of Timor-Leste is embedded in its National Health Sector Strategic Plan (2011–2020) (NHSSP) which envisages strengthening national research capacity for informative evidence-based health policy and decision-making. NHSSP further proposes establishment of an operational research centre to address health and system challenges and building capacity for applied health research at its National Hospital and other statutory health bodies. Ministry of health fully appreciates the need to promote health research to understand burden of disease and determinants of health and for developing and evaluating effective treatment and preventive interventions.

Timor-Leste has slowly strengthened its health research governance structure starting with establishment of Cabinet of Health Research and Development (CHRD) in 2009 as an independent body within Ministry of Health through a Ministerial decree. The key functions of CHRD included coordination and prioritization of research, capacity-building, ethical review and research database management. In addition to CHRD, Faculty of Health Sciences at the National University of Timor-Leste in Ministry of Education is an important part of research ecosystem in TLS.
However, overtime the research landscape has become complex with multiple authorities for research approval, legal barriers to conduct research by government functionaries, and no legal provision for data protection or guidelines for data sharing.

The process for developing National Health Research Strategy (NHRS) started in November 2021 with national health research capacity assessment followed by series of stakeholder consultations. Ministry of Health and Education review the draft NHRS in October 2022 followed by further stakeholder consultations. The draft NHRS was presented to Council of Directors in July 2023 and was finalized in September 2023.

Vision, mission and principles of NHRS: The vision of the NHRS is that “Evidence is generated and used for policy and programme development to improve health and well-being of People of Timor-Leste” with a mission of strengthening the national health research capacity and resource base to enable conduct of research of global standards to address health priorities of the country. The strategy views research as an investment and is based on the principles of equity, self-reliance, collaboration and partnership, innovations and translation of knowledge.

Objectives and expected outcomes of NHRS: The five main objectives of NHRS include 1) establishing an enabling governance and regulatory framework for health research 2) developing effective mechanisms for ensuring quality research 3) strengthening research capacity 4) research prioritization 5) and research translation. It is envisaged to set up a health research centre under the new National Public Health Institute and develop a publicly available health research agenda, establishing a research grant for health systems research and to strengthen the links between health research, health policy and programmes.

2.7.3 National Health Research Strategy: Bangladesh, Presenter: Dr Md Ruhul Amin, Director, Bangladesh Medical Research Council (BMRC)

BMRC founded in 1972 as an independent agency under the Ministry of Health and Family Welfare formulated the National Health Research Strategy in 2009 to promote the practice and conduct of research to improve human health and welfare of people in Bangladesh. Some of previous research contribution included introduction of ORS, treatment of malnutrition, discovering transmission pathway of Nipah encephalitis, snake bite and malaria research.
2.7.4 Group work: Developing a Regional Strategy for Health Research

1. Do the proposed building blocks of regional strategy make sense? What else should be included in it?

Most participants listed regional regulatory mechanisms, research priority setting, capacity-building, regional data sharing, resource allocation and funding, protection of human subjects, translation and implementation, collaboration and partnerships, evaluation and monitoring.

2. How should we evaluate the success of the regional research strategy? What should be the key milestones, indicators to monitor its implementation?

The participants listed that a set of inputs (number of countries having data sharing policies, number of countries have online data archives or number of countries that are able to track their research investments), presence of a regulatory framework including for ethical oversight, establishment of national priorities, availability of funding of research, presence of formal platform for linking evidence to policy, presence of research network/collaboration where justified; process (training for capacity-building); output (number of researches, trials, publications); and outcomes (changing policy and impact on health).

3. How may the Member States use the Regional Research Strategy to inform the National Research Strategies or for any other purpose?

Regional health strategy may help to serve the purpose of advocacy for specific policies and areas currently neglected in national strategies. This may also serve a tool to mobilize resources and guide the development of national policies, actions, research networks.

4. What should be the next steps to finalize the regional research strategy to get inputs from the Member States and to mobilize political support for research and innovation?

The next steps to develop a draft strategy based on discussions in the current meeting, followed by solicitation of feedback and inputs from all the Member States and finalizing the Strategy by incorporating all the inputs. Political engagement through consultation with MOH and other relevant stakeholders is must at all stages. The Strategy should be endorsed by Regional Committee of South-East Asia Region. Once developed the Regional Strategy should also be used for mobilizing funding and for engaging multiple stakeholders.
3. Recommendations and Conclusions

3.1 Performance of essential health research governance and management functions

1. Member countries will acknowledge that effective governance and management systems of a national health research are essential to ensure timely, quality, ethical and efficient health research.

   Essential governance and management functions shall include:

   (1) Identifying [regional] national priorities in health research including multidisciplinary research & steering research investments and research portfolios in that direction.

   (2) Protecting human research participants [Ethics oversight]

   (3) Creating and enabling mechanisms to ensure scientific rigor & quality research

   (4) Building, strengthening and sustaining national health research capacity

   (5) Creating and supporting systems to facilitate wider access and dissemination of all research outputs

   (6) Promoting and supporting national and cross-national research networks and intersectoral coordination of health research.

   (7) Mobilizing and monitoring financial resources for health research and steering research investments to national priorities

2. Appropriate bodies should be identified or created and assigned responsibility for discharge of these essential health research governance and management functions.

3. Human and financial resource needs to discharge these functions should be acknowledged as legitimate research costs by national and international funding agencies. Methods should be identified for their inclusion in funding applications and subsequent dispersal to appropriate stakeholders.

3.2 Building effective, transparent and resilient ‘fit for purpose’ National Health Research Ethics Systems: An essential research governance and management function

(1) NHRC or the research governance bodies should consider development and supporting REC systems through developing appropriate policies, standards and guidelines as one of their essential functions.
(2) NHRC or equivalent bodies should set harmonized ethical standards for health research in line with international standards and guidelines and should promote systems that facilitate application of these standards by adequately trained and resourced research ethics committees.

(3) Digital enablement of Research ethics review system: Development and promotion of use of online submission and review systems (similar to what is being used by journals) by individual RECs, preferably developing a single web-based national system linked to national health research registries and to other research governance functions with accounts for different RECs functional in the country allowing for central submission and application-tracking. As for many journals, the private sector has setup platforms that support multiple journals, similar systems may be explored for ERCS.

(4) SEARO ERC has developed a platform and using it for its own committee and may be provide to other interested member states.

(5) The human and financial resources required to perform these functions should be recognized and provided for as legitimate research costs by the research institutions themselves where these committees are situated, rather than recovering from each research project.

(6) Resilience, capacity and ability to flex responses: Uncertain levels of demand growth and evolving technological landscape warrants more flexible REC structures and processes with ability to opt in more members on a short notice and utilize the network capacity.

Efficient: ERC review system is able to ensure protection of human subjects while also ensuring timeliness at the lowest cost possible.

Effective: ERC review system is able to ensure protection of human subjects while also ensuring overall quality of research & reducing the research wastage.

Resilient system: ERCS are able to deliver in the changing technological and health emergencies environment.

Transparent: All stakeholders are aware of the transactions of ERCS to reduce duplication.

Core mandate of system:

- Having an additional external check (peer review) on quality of research before it is actually conducted.
- Fixing accountability on the institution in addition to on the individual researcher to protect the human research participants.
(7) Mechanisms that can realize the potential of research ethics committees to serve as a gateway to facilitation of other essential research governance functions such as research registration and data archiving should be explored.

**Goals for Member States:**

By the end of 2025:

- All Member States assign clear organizational responsibility for building national health research ethics systems including development of overarching policies, tools, national dashboards/databases of ERCs functioning in the countries.
- All Member States develop necessary policies and harmonized standards to be used by all the RECs operational in the country.

By the end of 2027:

- All Member States, individually or in partnership, have developed functional and accessible online RECs dashboards or databases which allows researchers to see the status of the RECs and research approved by them.
- Digitally enabled RECs, preferably as part of a centralized cloud-based system: At least half of the RECs functioning in the country especially in the public sector use online submission and review systems.

By end of 2030:

- All the ERCs functioning in the Member States use online submission and review systems.
- All ERCs are fully networked with elimination of duplicative review systems.
Fig. 7. The vision of online Centralized Interconnected National Research Ethics Review Systems

Current status

- Individual RECs managing submission & review processes manually using different review forms & standards
- Individual RECs managing submission & review processes through their own online systems
- Registration of RECs operating in a country at national level done manually as a standalone process
- Standalone Clinical trial registers requiring researchers to register pre or post approval by RECs

The vision

- Integrated single centralized cloud-based national e-EC system where all RECs can open their accounts and manage the review and submission system
- Harmonization of review standards and processes across RECs
- Tracking of key performance indicators-average time from submission to approval
- Automatic registry of all ERC functional in the country
- Generation of a research registry as research proposals approved by different RECs automatically get added to it, no separate registration requirement

Fig. 8. Theory of Change from essential research functions to better health outcomes

Theory of change: From performance of Essential Research Governance & Management functions to better health outcomes

- Monitoring research activity and investments; regular prioritization of future investments by low priority setting
- Digitally enabled cloud-based research ethics review system with virtual flexibility that generates a research registry
- Rapid training programs-Quality assurance before start of research (REC) reporting of results by all-Quick assurance at publication stage
- Digitally enabled archiving of all research outputs-flexibility Easy access to all outputs

1. Setting priorities in health research & steering research investments and portfolios in that direction.
2. Protecting human research participants, while ensuring timeliness and quality.
3. Creating and enabling mechanisms to ensure scientific rigor & quality research
4. Building, strengthening and sustaining national health research capacity
5. Creating and supporting systems to facilitate findability and wider access and dissemination of all research output
6. Promoting and supporting national and cross-national research networks

Essential Health Research Governance & Management functions

- Accessible evidence
- Quality evidence
- Fast research translation
- Facilitative research environment
- Better translation of research to products, policies, public goods

Better health outcomes

- Translation interventions
- No product > Availability
- Too expensive > Affordability intervention
- No acceptable > Accessibility intervention
- Not acceptable > Acceptability intervention

Research translation Scaling up Health Technology assessment

Research governance and management

Well-resourced organizational structures
Awareness of their roles, use of right tool, regular monitoring of their performance
3.3 Systematic Archiving and increasing access to public health research data: Realizing the full potential of public health data to generate better health

(1) All Member States and research stakeholder should formally recognize efficient and systematic archiving and management of public health databases and making databases accessible for wider and more effective use as important health research governance and management function.

(2) Each Member State should assign appropriate organizations the responsibility for development, overseeing and ensuring compliance with data archiving policies. These policies at the minimum require that databases generated from publicly funded health research must be systematically and securely archived and preserved. Scope of databases covered, and archiving arrangements adjusted as capacity and infrastructure develop.

(3) National health research strategies/plans should include as an explicit aim the development of the human and technical resources, skills, capacity and infrastructures needed to support data archiving, management and access.

(4) Collaboration and cooperation between different health research stakeholders both within national boundaries and beyond is essential if the goals of systematic archiving and wider access are to be realized. Research stakeholders (including but not limited to Member States (national policy makers and programme managers), research funding organizations, research managers, research ethics committees, research institutes and research publishers) should pledge to work together at national and international levels to develop an enabling environment and the consensus and mechanisms needed to realize the health benefits that efficient data archiving and more effective data use offers.

(5) Greater access to and (re)use of data should be promoted in line with three key principles:

- Increased data access must be EQUITABLE. The expectations of several stakeholder groups must be acknowledged and balanced: the primary researchers who generate the data; those who require the data for secondary research and analysis; the individuals who were research participants, and the funders and communities who seek health benefits.
Regional Consultation on Health Research Governance and Management in South-East Asia

- **Increased data access must be ETHICAL**, safeguarding privacy of research participants and minimizing the risks with the imperative to facilitate productive and efficient scientific use of the data to maximize public benefit.

- **Increased data access must facilitate EFFICIENT research**: improving the effectiveness of health research and accelerating the production of potential health benefit; reducing duplication and competition and increasing collaboration and skill-sharing.

(6) Global, regional and international collaboration and cooperation should be adopted as a fundamental principle in strategies aimed at the development of infrastructure, skills and capacity for the archiving and increased access to and use of public health databases.

Where practical and appropriate, technical infrastructures and repositories for secure long term data storage may be cost-effectively developed on a regional or subregional basis and shared by several countries.

Agreements should be pursued on common data formats and database architectures to maximize database compatibility.

(7) Given the many challenges involved, realistic and achievable goals should be set. In the first-place archiving requirements and moves towards increased access should be aimed at databases involving large population samples (national or subnational in scope), with broad utility (involving multiple health related domains) and potential for creating reference data sets (for example, may be combined with other databases to assess trends in conditions or services over time).

(8) Goals for Member States:

By end of 2025:

- All Member States adopt an explicit national policy on long-term preservation of and increased access to public health research data following the three principles outlined at # 5.

- All Member States assign organization/entity to be responsible for data preservation, management and accessibility.

- All Member States issue necessary policy and other directives to all research stakeholders to comply with the requirements for data preservation, management and accessibility.
By end of 2026:

- All Member States, individually or in partnership, have developed functional and accessible data repositories providing access to public health research data to the wider public health communities.

(9) Goal for research funders: By end of 2026:

- All international or national organizations funding research in SE Asia Region Member States have put in place policies and mechanisms to ensure long-term data preservation of and increased access to public health data generated by research funded by them.

3.4 Establishing a generic South-East Asian Regional clinical research network

(1) As part of developing **regional clinical trial infrastructure and readiness**, all Member States and research stakeholder should formally recognize establishing and supporting **publicly funded** national (where feasible especially in large countries) and **regional clinical research networks** as important health research governance and management function.

(2) The formation of Regional clinical research networks should be based on the recognition of its value in shared gains by Member States and embedded in shared commitments.

(3) Each Member State should designate **appropriate organizations as focal entity to develop such national networks** and coordinate their participation in and support of Regional networks. This designated entity should coordinate in-country stakeholders for improving the functionality and impact of this network.

(4) This regional network will support the clinical research of relevance to the Region that can be undertaken by public or private institutions by applying to the network.

(5) The Governance structure for the Network may be developed in consultation with the designated institutions from all the Member States based on principles of representativeness, respect for national priorities and mechanisms, and the collective decision-making process, and clear accountability framework.

(6) The network may be funded through a Regional Fund on health research financed by all the Member States (in kind or in monetary terms) and by external partners.
(7) If any of individual Member States have their own national networks, they can integrate the same networks into the South-East Asian Regional network. [Regional network building on the national networks]

(8) The SOP for the network will be developed that will emphasize common protocols, single ERC approvals and common data management platforms and harmonization of regulatory requirements, and accelerated market access in all Member States.

(9) Goals for Member States:
By end of 2024:

- Political commitment/buy-in mobilized from all Member States for establishing a multi-disease South-East Asian Regional Clinical Network

By end of 2025:

- Member States have developed their national networks where feasible.
- In consultation with all the Member States, the overall network strategy developed with specification of governance structures, standard operating procedures and operational modalities.

By end of 2026:

- First study got started.
- Sustainability plan developed.
4. **Feedback from Participants**

An online Feedback form Regional Consultation on Health Research and Governance in SEARO was sent to all participants. A total of 39 responses were received: 65% Member States participants, 23% WHO staff, 8% partner agency and 5% WHO Collaborating centers.

A total of nine questions were asked requiring responses on a scale of 1 to 5. (1 being not appropriate at all and 5 being very appropriate), the following table shows the range, mean and percentage of participants giving highest score of 5 (very appropriate).

<table>
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<tr>
<th>Questions</th>
<th>% Respondent with highest score (5)</th>
<th>Mean Score</th>
<th>Range</th>
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<tbody>
<tr>
<td>How relevant was the regional consultation to country research systems?</td>
<td>74</td>
<td>4.72</td>
<td>(3-5)</td>
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<tr>
<td>How useful was the session on &quot;Essential research governance and management functions&quot;?</td>
<td>62</td>
<td>4.62</td>
<td>(4-5)</td>
</tr>
<tr>
<td>How useful was the session on &quot;developing efficient, resilient and transparent research ethics system&quot;?</td>
<td>62</td>
<td>4.56</td>
<td>(3-5)</td>
</tr>
<tr>
<td>How useful was the session on &quot;research data sharing&quot;?</td>
<td>74</td>
<td>4.74</td>
<td>(4-5)</td>
</tr>
<tr>
<td>How useful was the session on &quot;national and regional clinical research networks&quot;?</td>
<td>62</td>
<td>4.54</td>
<td>(3-5)</td>
</tr>
<tr>
<td>How useful was the session on &quot;national and regional research strategies&quot;?</td>
<td>62</td>
<td>4.59</td>
<td>(3-5)</td>
</tr>
<tr>
<td>How did you find the number and content of presentations made during the consultation? 1 being not appropriate at all and 5 being very appropriate.</td>
<td>54</td>
<td>4.51</td>
<td>(3-5)</td>
</tr>
<tr>
<td>How will you rate the group work activities in terms of duration, structuring and guidance provided.</td>
<td>67</td>
<td>4.64</td>
<td>(3-5)</td>
</tr>
<tr>
<td>The content and discussions undertaken during the regional consultation was helpful and suitable for my country context?</td>
<td>56</td>
<td>4.54</td>
<td>(3-5)</td>
</tr>
<tr>
<td>How satisfied were you with communication regarding the consultation?</td>
<td>64</td>
<td>4.64</td>
<td>(4-5)</td>
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### Day 1: Tuesday, 7 November 2023

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<tr>
<th>Time</th>
<th>Title</th>
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<td>8:30–9:00</td>
<td>Registration</td>
<td>Secretariat</td>
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#### Opening Session

- **9:00–9:15** Opening remarks
  - Dr. Pem Namgyal, Director, Programme Management on behalf of Regional Director, WHO/SEARO

- **9:15–9:30** Welcome remarks & Brief introduction of participants
  - Dr Suman Rijal, Director, Communicable Diseases

#### Session 1: Setting the scene: governance and management of health research

**Moderator:** Dr. Manju Rani  
**Rapporteur:** Dr. Nora, WCO Indonesia

- **9:30–10:00** The Status of governance and management of research in WHO South-East Asia Region—the key findings from National health research assessments 2023
  - Dr Anand Krishnan

#### Session 2: Improving governance and management of health research: discussing and agreeing on the way ahead

**Moderator:** Kavita Singh, DNDi  
**Rapporteur:** Dr. Nora (WCO INO) & Dr. Helble (HQ)

- **10:30–10:40** Brief introduction to group work objectives
  - Dr. Manju Rani, RA (R&I) SEARO

- **10:40–11:30** Group work 1: What constitutes Essential Research Governance and Management functions that must be performed at national level by appropriate designated organizations
  - 3 groups-each group to choose their own moderator and rapporteur

#### Session 2b: Current country experiences in using different tools/strategies to improve governance and management of health research and reporting back from the group work

**Moderator:** Kavita Singh, DNDi  
**Rapporteur:** Dr. Nora and Dr. Helble

- **11:30–11:45** ➢ Indonesia—Value addition and benefits from Indonesia Clinical Trial Register
  - Prof Indi, BRIN, Indonesia

- **11:45–12:00** ➢ NIH World Report system for financial tracking  
  - Dr. Nandita Chopra, NIH, USA

- **12:00–12:30** ➢ Keynote address: Role of WHO in Research and Innovation
  - Dr Jeremy Farrar, Chief Scientist, WHO
**Day 1: Tuesday, 7 November 2023 (Continued…)**

| Session 3: Building effective, efficient, transparent and resilient National Health Research Ethics Review systems: feasibility and options | Moderator: Kavita Singh, DNDi  
Rapporteur: Dr. Shuchi Soni, WCO Timor-Leste |
<table>
<thead>
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<tbody>
<tr>
<td>13:30–14:30 Reporting back from the group work-essential research and governance functions</td>
<td>Reporting back from groups</td>
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</table>
| 14:30–15:30 **Group work 2:** Tools/ options to strengthen the research ethics systems in the countries to ensure ethical, quality, efficient research. Brief introduction to group work objectives | Dr. Manju Rani, RA(R&I)  
WHO/SEARO |
| **Session 3b: Specific Country experiences/status on strengthening and streamlining of national research ethics review systems** | Moderator Dr. Kavita Singh DNDi  
Rapporteur: Dr. Nora, WCO Indonesia |
| 1600–16:15 Nepal NHRC ERC online submission –the experience | Ms. Namita Ghimire Nepal NHRC |
| 16:15–16:30 India national ERC registration system (Naitaik): what is it, gains made, and way forward | Roli Mathur, ICMR, WHOCC |
| 16:30–16:45 India e-EC system – gains made and way forward | Dr. Nitya Wadhwa, THSTI, WHO CC |
| 16:45–17:30 **Reporting back from the groups and closing of day 1** | Each group’s rapporteur |
| 10 min each by each of the 3 groups | |

**Day 2: Wednesday, Nov 8: Maximizing the full potential of public health research data to generate better health**

| Session 4: Setting the scene: data sharing in public health research (rationale, issues and potential challenges) | Moderator: Timothy Jinks (Wellcome Trust)  
Rapporteur: Dr. Nabeel, WCO MMR |
|---|---|
### Regional Consultation on Health Research Governance and Management in South-East Asia

<table>
<thead>
<tr>
<th>Time</th>
<th>Session 5: Group work 3: data-sharing: status, experience and policies</th>
<th>Moderator</th>
<th>Rapporteur</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:30–10:45</td>
<td>Open data platform, India experience</td>
<td>Timothy Jinks</td>
<td>Dr. Nabeel, Dr. Wei</td>
</tr>
<tr>
<td>10:45–11:00</td>
<td>Sri Lanka data sharing</td>
<td>Dr. S. Samarakoon, Sri Lanka</td>
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**Session 5: Group work 3:** Desirability, feasibility, tools, options for systematic archiving and wider sharing of research data

<table>
<thead>
<tr>
<th>Time</th>
<th>Session 6: Data sharing: next steps, timeline and recommendations</th>
<th>Moderator</th>
<th>Rapporteur</th>
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<tbody>
<tr>
<td>11:00–12:30</td>
<td>Group work 3: Desirability, feasibility, tools, options for systematic archiving and wider sharing of research data</td>
<td>Timothy Jinks</td>
<td>Dr. Nabeel, Dr. Wei</td>
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**Session 6:** Data sharing: next steps, timeline and recommendations

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Moderator</th>
<th>Rapporteur</th>
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<tbody>
<tr>
<td>1:30–3:30</td>
<td>Group presentations and sharing of experiences from external organizations</td>
<td>Dr. Nandita Chopra, Timothy Jinks</td>
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<tr>
<td></td>
<td>➢ Reporting back from Groups</td>
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<td></td>
<td>➢ Data sharing policies NIH</td>
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<td></td>
<td>➢ Data Sharing policies at Wellcome Trust</td>
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**Session 6: Data-sharing: next steps, timeline and recommendations (continued):**

<table>
<thead>
<tr>
<th>Time</th>
<th>Finalize of draft recommendation from Day 2 (essential function on research governance and management, research ethics and data sharing)</th>
<th>Moderator</th>
<th>Rapporteur</th>
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<tbody>
<tr>
<td>4:00–5:00</td>
<td>Draft recommendation statement</td>
<td>Timothy Jinks</td>
<td>Dr. Nabeel, Dr. Wei</td>
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</table>

**Day 3: Thursday, 9 November**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session 7: Regional Clinical Research networks-what, how, why</th>
<th>Moderator</th>
<th>Rapporteur</th>
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</thead>
<tbody>
<tr>
<td>9:00–9:30</td>
<td>Setting the scene: regional research networks: key issues</td>
<td>Timothy Jinks, Welcome Trust</td>
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<tr>
<td>9:30–10:00</td>
<td><strong>Country/ Regional experiences/status</strong></td>
<td>Dr Hsu Li Yang, National Singapore University</td>
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<td></td>
<td>Singapore National University – AMR Regional Research Network</td>
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<tr>
<td>10:00–10:30</td>
<td>India national research network: 'INTENT - Indian Clinical Trial and Education Network'</td>
<td>TBC, ICMR, India</td>
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<tr>
<td>11:00–12:30</td>
<td><strong>Group work 4:</strong> Desirability, feasibility, options for establishing regional clinical research networks?</td>
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</table>
### Session 8: Conclusion 1: Review the conclusions from the group work:

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<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1:00–2:00</td>
<td>Groups reporting back to plenary (10 min each), following by discussion</td>
</tr>
<tr>
<td>2:00–3:15</td>
<td>Collecting developing, draft recommendation on regional research networks. Reviewing the final overall recommendations including goals/action plan</td>
</tr>
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</table>

**Chair:** Dr. A K SB De Alwis (Sri Lanka)  
**Rapporteur:** Dr. Pushpa (SEARO)

### Session 9: Conclusion 2: discussion and agreement on plan to follow-up on the implementation of outcomes of consultation

**Chair:** Dr NLP Indi Dharmayanti  
**Rapporteur:** Dr. Anand Krishnan

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>3:45–5:00</td>
<td>Discussion on Key recommendations from the past two days</td>
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<td>Closing session</td>
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### Day 4: Friday, 10 November: Developing Regional Research Governance and Management strategy

**Session 7: Key Building Blocks of Regional Research Strategy**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>9:00–9:30</td>
<td>Key building blocks of the regional research strategy</td>
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<tr>
<td>9:30–10:00</td>
<td>Theory of Change framework for Regional Research Strategy</td>
</tr>
<tr>
<td>10:30–12:00</td>
<td>Group work 5: Monitoring and evaluation framework for regional strategy</td>
</tr>
</tbody>
</table>

**Chair:** Dr NLP Indi Dharmayanti  
**Rapporteur:** Dr. T. Moyana

### Session 8: Developing National Research Strategies—current experience in developing them and their impact

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>13:00–13:45</td>
<td>Reporting back from the groups</td>
</tr>
<tr>
<td>13:45–14:00</td>
<td>Timor-Leste</td>
</tr>
<tr>
<td>14:15–14:45</td>
<td>Bangladesh</td>
</tr>
<tr>
<td>14:45–3:30</td>
<td>Reviewing the draft regional research strategy, overall recommendations including goals/action plan—and next step to finalize it.</td>
</tr>
</tbody>
</table>

**Chair:** Dr. Md Ruhul Amin, BMRC  
**Rapporteur:** Dr. T. Moyana

### Session 9: Closing Session

**Co-Chairs:** Professor Dr Md Ruhul Amin; Dr NLP Indi Dharmayanti

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>3:45–4:30</td>
<td>Discussion on follow-up mechanisms to monitor implementation of the consultation outcomes</td>
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</table>

Closing remarks by Director, CDS / WHO Regional Director
Annex 2

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Annex 3

Opening remarks by the Regional Director

Welcome to this Regional consultation on improving health research governance and management in WHO South-East Asia Region.

Developing effective public health policies and programmes is primarily based on timely and context-appropriate evidence derived from research.

But is research as timely, credible and efficient as it could be?

As per an editorial published in British Medical Journal in May 2020, it was estimated that before the pandemic, up to 85% of research was wasted because of poor questions, poor study design, or inefficiency of regulation and conduct. Many of these problems got amplified during COVID-19 with time pressures and inadequate research infrastructure.

This high research waste has created a paradoxical situation. While there has been substantial continuous increase in the ‘research publications’ to the point of “information overload”, yet policy makers often complain about inadequate evidence to inform clinical and programme decisions. Systematic reviews tell time and time again that the evidence base is inadequate.

For years there have been growing calls for more spending on health research.

We are all in favour of that, of course, but we must not lose sight of the need for ‘quality’ research and better use of limited resources.

Investment in research is like any other investment: a return is expected. Yet often the returns on health research investments are not monitored or documented.

And this brings me to the focus of this regional consultation: better governance and management of health research.

Member States in our Region have made some progress in this area. Most Member States in the Region now have dedicated research governance structures in the form autonomous national health or medical research councils or full-fledged Department of Health Research, have undertaken research prioritization exercises and have developed national health research strategies.

But the question is how are these governance and management structures functioning? Are they able to guide and monitor research? Are they able to ensure that health research
conducted in their country addresses the most public health issues faced by its citizens. Are these structures able to reduce the research waste by preventing duplication, non-reporting, non-use of research findings?

The experience during COVID-19 pandemic does not support this. The uncoordinated ‘research chaos’ during the pandemic involving conduct of duplicative poorly designed clinical trials, each authorized by the national regulators, had a substantial negative impact on global health.

It clearly shows that much can be done to improve the overall governance and management of health research and this in turn can improve credibility, transparency, efficiency and quality of health research.

The result: better health outcomes.

One of other areas that require more discussion and consensus are the effective use of public health data generated by research and public health programmes. All too often data are treated as the property of individual researchers, or they languish in a computer in a government office.

One initiative that has played a key role in advancing public health in developing countries is the ‘Demographic & Health Surveys’, started by USAID in the late 1980s. Analysed by hundreds of researchers and programme managers, the databases generated by these surveys have demonstrated trends in infant and maternal mortality rates over time, highlighted trends in diseases and identified changes in care seeking behaviours. What sets the “Demographic & Health Surveys” apart from other less successful initiatives is its ‘open data policy’.

The databases from Demographic and Health Surveys have been routinely archived and made freely available to the wider research community. However, data from countless other surveys conducted in the Member States are not easily accessible to public health researchers and remain highly underutilized. I am happy to note that this consultation is going to discuss this important issue.

COVID-19 pandemic revealed another gap: limited research infrastructure to enable collaboration and coordination of research across multiple sites and multiple countries. Well resourced multicountry research networks with previously identified trial sites with trained staff and other critical infrastructure, agreed benefit sharing arrangements can provide the much-desired warm base to not only start a trial quickly and efficiently but may ensure much faster update of the results and more equitable sharing of the benefits.
Improving research governance and management is critical for addressing current and future public health challenges including various health emergencies. Recently the Seventy-fifth World Health Assembly also adopted a resolution to improve the coordination and quality of clinical trials and to avoid duplication of research. I understand, developing, managing and governing regional research networks is on the agenda of this consultation.

I hope this Regional Consultation involving national health research councils, experts, partners, will examine these issues in depth, and produce practical recommendations that can be implemented by WHO and all the Member States in the near future.

With this, I officially open this regional consultation and wish you a very productive and successful meeting.

And I hope you have an enjoyable stay in Delhi.
Regional Consultation on Health Research Governance and Management in South-East Asia

7-10 November 2023, Delhi, India