



**Towards an effective mechanism for improving coordination of investments in clinical research, and research capacity strengthening in low and middle-income countries (LMICs)**

***Consultation Background Paper***

*Prepared for the ESSENCE Working Group for the development of a mechanism for reviewing investments in clinical research capacity building in LMICs (WGRI)*

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*Note: This paper was prepared as input to ongoing consultations aimed at achieving greater effectiveness in coordinating research capacity strengthening investments in LMICs. The content of this document is based on literature reviews and key informant interviews which though extensive, were by no means exhaustive, and only represent a part of the broad consultations required for meaningful and actionable recommendations on this subject to be made, or final decisions reached. The paper does not represent the final output of the working group.*

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# EXECUTIVE SUMMARY

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## **Context**

This background paper is prepared in furtherance of *Recommendation 12* of the **Task Force on Strengthening Country Capacity for Vaccines Research and Development (IVTF)**, convened by the World Bank (WB) and the Coalition for Epidemic Preparedness and Innovation (CEPI) in October 2017 to develop a set of recommendations on strategic investments that can strengthen clinical research and clinical trial capacity in low- and middle-income countries (LMICs). Recommendation 12 requires, ESSENCE, in collaboration with the Global Coordination Mechanism to articulate a mechanism that permits a thorough review of current and planned investments in research capacity strengthening in LMICs, by the end of 2019. This mechanism is expected to ensure synergy at country and regional levels, with respect to investments in research capacity strengthening in these countries.

The purpose of this paper is to enable participants in the March 2019 consultative session, efficiently arrive at a common position on the *why, what and how* of the envisaged mechanism, to inform actionable recommendations.

The primary thesis of this paper is that greater synergy and enhanced coordination between and amongst funders of health research, research organisations, users of clinical research, and other key actors in LMICs can be achieved through an effective mechanism, that improves multi-stakeholder engagement, and provides a common set of principles, metrics, data and standards to better inform investment decisions on clinical research capacity building and strengthening.

## **Barriers to surmount**

Based on literature reviews and expert interviews, the paper highlights two critical problems, which currently militate against effective coordination of clinical/health research investments - (a) inherent difficulties in setting and agreeing on capacity strengthening priorities for LMICs due to lack of quality data on what health research and capacity strengthening programs is being conducted or planned, and lack of information on the current capacity at national and institutional level; (b) complexities in the institutional landscape for health R&D which limit effective collaboration within and among multiple institutions. The inherent complexities are also apparent in the diversity of needs and requirements by different stakeholder groups.

## **Key elements of the current landscape and implications for the mechanism**

The paper undertakes an extensive review of the current landscape for assessing clinical research capacity and investing in clinical research capacity strengthening in LMICs. Based on this review, it highlights for consideration, three defining elements which should influence the design of a more effective mechanism:

1. *Absence of strong nationally-owned systems for assessing/evaluating clinical/health research capacity and sharing the results of such assessments;*
  2. *Use of multiple, discrete externally designed systems to assess clinical/health research capacity and/or review research capacity strengthening investments in LMICs without enough alignment in objectives and data sets used to inform such assessments/reviews; and*
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3. *Absence of organizations/entities that have a broad enough remit to lead/drive a holistic approach to coordination, yet structurally and functionally simple enough to navigate the institutional complexities inherent in the landscape*

The implication of these defining elements of the landscape is that to design a more effective mechanism, participants at the consultation will need to:

1. Consider ways to improve the definition of competencies and standards that reflect capacity, and ways to encourage usage and uptake of assessment frameworks by LMICs, to increase the availability of quality country-generated data on prevailing capacity and simplify gap analysis/intervention design.
2. Figure out how to address the institutional complexity issue, given that data-sharing systems that are designed to meet the needs of all stakeholders run the risk of being either too simple to satisfactorily address these needs or becoming too complex to be efficiently and cost-effectively maintained and kept relevant. Finding the right-subset of stakeholder needs that can be met to create the most impact and the right subset of data to optimize and make more meaningful should be considered in depth. So is designing the right format for the presentation of data to maximize its utility.
3. Decide on the appropriate organizational entity within which this mechanism should be embedded and resolve important questions of how it is governed and funded without negatively impacting its LMIC focus, organizational agility and responsiveness, and neutrality. Achieving collective accountability amongst participating organisations in a way that is non-threatening yet effective, should be a priority.

### ***Designing the mechanism/making recommendations***

Effective deliberations to recommend a better mechanism will require stakeholder alignment around the desired end state that the mechanism is expected to bring about, agreement on a set of guiding principles, and a clear framework for thinking about how to structure the recommendations to realize the envisaged mechanism. To support this, this paper presents a few potentially useful case studies (mainly outside the health research ecosystem) to enrich the ideation process, and in the final section, proposes some language on the desired end-state, suggests a few guiding principles, and then lays out a framework to guide the collective process of developing recommendations at the March 2019 consultation session.

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## 2 INTRODUCTION AND CONTEXT

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### 2.1 BACKGROUND PAPER: CONTEXT

This background paper is prepared in furtherance of *Recommendation 12*<sup>1</sup> of the **Task Force on Strengthening Country Capacity for Vaccines Research and Development (IVTF)**, convened by the World Bank (WB) and the Coalition for Epidemic Preparedness and Innovation (CEPI) in October 2017 to develop a set of recommendations on strategic investments that can strengthen clinical research and clinical trial capacity in LMICs<sup>2</sup>. It is prepared to inform an upcoming multi-stakeholder consultative session (scheduled for early March 2019) convened by the ESSENCE for Health Research Working Group<sup>3</sup>, aimed at articulating an effective mechanism that permits a thorough review of current and planned investments in clinical research capacity strengthening in LMICs, to make global coordination more effective.

**Recommendation 12:** By end 2019, ESSENCE, in collaboration with the Global Coordination Mechanism and reinforced with additional LMIC representation, should articulate a mechanism that permits a thorough review of current and planned investments in research capacity strengthening. This should be done in consultation with major external funders of clinical research (including those involved in capacity strengthening of network, laboratory, ethics, and regulatory capability). This collaborative mechanism should ensure synergy at country and regional levels, and streamline the administrative burden experienced by institutions dealing with multiple research funders.

The primary thesis of this paper is that greater synergy and enhanced coordination between and amongst funders of health research, research organisations, users of clinical research, and other key actors in LMICs can be achieved through an **effective mechanism, that improves multi-stakeholder engagement, and provides a common set of principles, metrics, data and standards to better inform investment decisions on clinical research capacity building and strengthening**. To enable participants in the March 2019 consultative session, arrive at a common position on how the above can be realized, this paper provides synthesized data on the landscape of clinical research capacity and research capacity strengthening in LMICs, with respect to coordination of research investments in LMICs through various existing mechanisms. Based on this landscape review, the paper highlights key issues and existing gaps, that should inform effective deliberation on what an effective, sustainable mechanism could look like. The paper also suggests a few strategic alternatives for consideration in the design of an effective mechanism for greater coordination of clinical research capacity strengthening investments in LMICs.

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<sup>1</sup> See Appendix for the full set of recommendations in the report. Read the full report here:

<http://documents.worldbank.org/curated/en/120551526675250202/pdf/126338-REVISED-27231-IVTF-Report-reduced.pdf>

<sup>2</sup> The report of the task force, titled Money and Microbes: Strengthening Research Capacity to Prevent Epidemics, was launched at the World Health Assembly, May 2018

<sup>3</sup> ESSENCE for Health Research Working Group for the development of a mechanism for reviewing investments in clinical research capacity building in LMICs (WGRI) was convened in October 2017 to drive the implementation of Recommendation #12

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The paper follows an analytical approach to providing the evidence needed to inform deliberations at the consultative session by seeking to address the following key questions in sequence:

1. Why does the world need this mechanism? What are the major gaps or barriers affecting effective coordination of investments in clinical research capacity strengthening in LMICs that it seeks to address?
2. What could an effective mechanism look like? How should it be envisioned?
  - a. Who would be the main users? What are their needs and how will they benefit?
  - b. What should be the ideal scope? What are the key actions envisaged and related components?
3. What is the landscape of assessing clinical research capacity and clinical research capacity strengthening in LMICs presently? What are the implications for designing an effective mechanism?
4. What are the existing mechanisms for coordinating clinical research investments into LMICs and what is their scope? What are the key issues and gaps limiting their effectiveness in coordinating investments?
5. What models for investment coordination/review mechanisms from within or outside the health research ecosystem can we learn from to make effective recommendations on the envisaged mechanism?

## 2.2 DEFINITION OF KEY TERMS

1. **Clinical Research:** Clinical research is a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health. Clinical Research embraces a continuum of studies involving interactions with patients, diagnostic clinical materials or data, or populations.<sup>4</sup>
2. **Clinical Research Capacity:** Though narrow in scope by theoretical definition, this paper defines clinical research capacity holistically as part of the big picture of capacity for health research in general, which is now widely acknowledged as the linchpin of effective and efficient health systems. Emphasis is on capacity for sustainable clinical research, and the required fundamentals such as infrastructure, education, legal and regulatory framework, and the ability to conduct clinical research during outbreaks. Accordingly, references to clinical research capacity in this paper lie on a spectrum between a narrow focus on clinical and behavioral research and more broadly other critical aspects of health research including biomedical research, population health research, and some aspects of health policy and systems research.
3. **Research Capacity Strengthening:** This has been formally defined as “any effort to increase the ability of individuals and institutions to undertake high-quality research and to engage with the wider community of stakeholders”<sup>5</sup>. For the purposes of this paper, the definition is broadened to include

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<sup>4</sup> Clinical Research: A National Call to Action, November 1999, US National Institutes of Health

<sup>5</sup> Seven principles for strengthening research capacity in low- and middle-income countries: simple ideas in a complex world; ESSENCE Good Practice Document

‘capacity building’ which is typically distinguished from ‘capacity strengthening’ by its use only in contexts where capacity is or was non-existent.

## 2.3 EXAMINING THE RATIONALE: GAPS AND BARRIERS LIMITING EFFECTIVE COORDINATION

Within the last two decades, concerted efforts have been directed towards finding effective ways to actualize clinical research capacity strengthening to improve the performance of national health research systems in low- and middle-income countries (LMICs). A significant proportion of these efforts have and continue to go into training and supporting individual investigators, enhancing the capacity of research institutions, strengthening health research leadership and regulatory capacity at national level, and improving the efficacy of collaborative research across these countries. A diverse set of actors have been involved with funding and resourcing these efforts. These include key organizations conducting research, pharmaceutical and biotechnology companies, academic institutes and universities, product development partnerships, research focused foundations/charitable organisations, and governmental development agencies. The sheer diversity in the number of actors, and the fact that many actors play across multiple roles makes the global institutional landscape for health research particularly complex.

Given this complexity, rising global interest in increasing the quantum of financing for clinical research in LMICs has been accompanied by calls for better coordination of health research relevant to developing countries, to ensure that scarce funds are being efficiently allocated. The demand for better coordination has also been driven by the need to avoid wasteful duplication of efforts, with several groups ‘addressing the same objective or following the same research paths in isolation from each other’<sup>6</sup>, limiting their overall impact on LMIC national health research systems. The primary purpose of coordination in this context has been to ensure that ‘new drugs, vaccines and diagnostics needed to treat diseases that are prevalent in low- and middle-income countries are developed and are safe, effective, affordable and suitable for the conditions in which they will be used, thereby contributing to better health and health equity globally’<sup>7</sup>. Critically important here is the need to ensure that a minimum level of capacity is available across all countries such that “holes in the map” are avoided, and weaknesses in one country do not unduly expose regional health systems to greater risk. Secondary objectives include avoiding unnecessary duplication of effort and wasted funding, ensuring that urgent or neglected areas become priorities, by assisting policy-makers and donors in setting and managing their priorities; facilitating better cooperation between the public and private sectors; and promoting the inclusion of a wider range of actors, such as by ensuring the involvement of researchers in low- and middle-income countries in finding solutions to problems assessed as relevant for them as part of research capacity strengthening in those countries<sup>8</sup>.

### *High level chronology of efforts to better coordinate clinical/health RCS in LMICs*

Successive commissions and conferences on health research have made recommendations on improving coordination and taken necessary actions. This section outlines in brief how some of these recommendations and actions have evolved/influenced the present landscape.

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<sup>6</sup> Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination; *Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination*; 2012; World Health Organization

<sup>7</sup> Research and Development Coordination & Financing: Report of the Expert Working Group; 2010; World Health Organization

<sup>8</sup> Ibid 6



- The Commission on Health Research for Development (CHRD) recognized the need for “...a mechanism to monitor the progress of research on developing-country needs and to identify unmet needs...”<sup>9</sup> which led to the emergence in 1993 of the Council on Health Research and Development (COHRED) as a support mechanism for countries in areas such as health research system assessment and development, policy development, priority-setting and research communication.
- The Ad Hoc Committee on Health Research Relating to Future Intervention Options in 1996 made a similar recommendation<sup>10</sup>, leading to the creation of the Global Forum for Health Research (GFHR) in 1998. The GFHR was merged with COHRED in 2010.<sup>11</sup>
- TDR, the Special Program for Research and Training in Tropical Diseases, established more than 40 years ago is in itself a global program of *scientific collaboration* that helps facilitate, support and influence efforts to combat diseases of poverty. It is **hosted** at the World Health Organization (WHO) and is **sponsored** by the United Nations Children’s Fund (UNICEF), the United Nations Development Program (UNDP), the World Bank and WHO. TDR is **currently funded** through financial core contributions by National Agencies from 15 countries, plus WHO as well as by specific project funding from 3 other organizations. As well as being a collaboration of many States, TDR is involved in several initiatives which relate to coordination and/ or capacity-building, including the African Network for Drugs and Diagnostics Innovation (ANDI), and the Initiative to Strengthen Health Research Capacity in Africa (ISHReCA)<sup>12</sup>.
- ESSENCE (Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts) on health research initiative was established following a meeting in 2008 in Stockholm attended by a number of funding organizations. The initial executive group was made up of the following organizations: the United Kingdom Department for International Development (DFID), International Development Research Centre (IDRC), the Ministry of Foreign Affairs of the Netherlands, Norwegian, Agency for Development Cooperation (Norad), the Swedish International Development Cooperation Agency (Sida) – plus the Bill & Melinda Gates Foundation and the Wellcome Trust. TDR was requested to act as the secretariat for ESSENCE.
- Further evidence of collective action and investment to improve coordination include the WHO/World Bank/UN Special Programme of Research, Development and Research Training in Human Reproduction (HPR); the International Clinical Trials Registry Platform (ICTRP) which is aimed at increasing the availability of structured information on clinical trials; and the Global Coordination Mechanism of the R&D Blueprint (GCM) launched in 2017<sup>13</sup>

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<sup>9</sup> Ibid 6

<sup>10</sup> Ibid 6

<sup>11</sup> A World Bank evaluation in 2009 noted: “...but it is not clear that the GFHR has substantially influenced the level and allocation of total global health research expenditure. Its core advocacy expenditures of US\$ 3.5 million a year could hardly be expected to have a substantial impact on the level and allocation of the current world total of US\$ 160 billion in annual spending on health research...The Forum does not appear to have had a significant impact on research priority setting within given allocations. This is especially the case at the global level which is the core of its mission.” Ibid 6

<sup>12</sup> Review by the Consultative Expert Working Group on Financing & Coordination for Health R&D of initiatives of the WHO aimed at improving coordination noted that whilst they have been useful to varying degrees, they “have overlapping objectives but separate governance arrangements”, arguing that there is scope for rationalization.

<sup>13</sup> Meeting Summary Notes: Establishing a Global Coordination Mechanism of R&D to prevent and respond to epidemics – Toward implementation of the GCM; [https://www.who.int/blueprint/what/improving-coordination/GCM2017\\_meetingsummary.pdf?ua=1](https://www.who.int/blueprint/what/improving-coordination/GCM2017_meetingsummary.pdf?ua=1)

- Several other efforts at improving coordination have been driven by organisations outside of the WHO, most actors working either in isolation, or as part of small collaborative groups of sub-sets of organizations with shared goals. These include but are not limited to the Product Development Partnerships (PDP) Funders Forum, the Heads of International Research Organizations (HIROS), the International Forum of Research Donors (IFORD).
- The European and Developing Countries Clinical Trials Partnership (EDCTP) is a collaboration between European Union States and African States. The collaborative program funds clinical research to accelerate the development of new or improved interventions against several poverty-related infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials. The initiative receives funds from the European Commission to be matched by European & Member States.

### *Summary of key barriers to better coordination of clinical/health RCS in LMICs*

While there is acknowledgement within the scientific research community that some progress has been made in improving coordination of clinical research capacity over the past two decades, there is also an admission that several of the problems that necessitated the early efforts aimed at improving coordination are still present. Some of the critical barriers mentioned in literature are outlined below:

1. **Inherent difficulties in setting and agreeing on capacity strengthening priorities** – Currently, there is no system to systematically and periodically map what health research is needed in LMICs vis-à-vis current capacity of LMIC countries and detail the implications for capacity strengthening. Although ‘substantial progress has been made in evaluating the burdens of existing health problems, the need for new knowledge and products is only assessed on an ad-hoc basis and for a selected number of diseases’<sup>14</sup>. There is also no system to facilitate the prioritization of LMIC health research needs and agree strategic focus areas. The ability to map needs, identify capacity gaps, and implications for capacity strengthening, and determine priorities is currently limited for the following reasons:
  - a. **Data availability and utility:** Limited effective data sharing on what health research is being conducted, and what capacity strengthening programs or initiatives are ongoing. There is a dearth of data on what investments in research/research capacity strengthening are already planned, which limits the predictive value, and utility, of existing data sets. The absence of forward-looking data is partly systemic, because large funders of scientific research and research organizations adopt a competitive approach to allocating research investments, hence their portfolios are shaped by the source of successful proposals, as against pre-defined priority disease areas or target countries. These extant organisational norms conflict with traditional ‘international development

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<sup>14</sup> “The mismatch between the health research and development (R&D) that is needed and the R&D that is undertaken: an overview of the problem, the causes, and solutions”; Roderik F. Viergever (2013)

organizations' who fund research in LMICs and have portfolio shaped by a pre-defined agenda, with implications for utility and availability of data.

- b. **Data consistency and integrity:** The absence of an effective clinical research data management arrangement that enables clinical research capacity considerations for LMICs to be informed by a consistent set of data. Use of disparate data sets by different actors creates a degree of information asymmetry that mitigates against reaching harmonious, forward-looking decisions on research capacity investments.
  - c. **Capacity assessment practices:** The absence of a widely adopted, standard system for assessing/measuring clinical research capacity, especially at the institutional and country/national level. In the absence of common metrics and indices, stakeholders adopt proxy measures, leading to inaccurate signaling of prevailing capacity levels, and poor articulation of capacity gaps. This issue has been widely acknowledged, and is the subject of *Recommendation 5*<sup>15</sup> of the aforementioned IVTF Task Force report, yet concrete action to improve this is yet to gather traction.
2. **Inherent complexities in the institutional environment:** As there's currently no truly recognized global coordination mechanism for health research capacity strengthening, there's currently an understanding that all actors are "jointly responsible" for ensuring that coordination occurs and is effective<sup>16</sup>. The diversity of the landscape and the key institutions, however, makes this idea impractical. Reasons include:
- a. **Differing remits and multiple points of accountability:** For example, National public funders of health R&D have often been established under national laws, have nationally focused remits, and are accountable to the parliament of their home countries, and hence are not usually able to invest in research/research capacity building that are not tightly linked to their national and/or political interests. International development organisations that spend Official Development Assistance (ODA) on health R&D have restrictions that impact how they spend, as do multilaterals, including remits that are limited to a specific set of diseases. This affects the efficacy of attempts at coordination, as coordination mechanisms are unable to directly influence tangible and sustained behavior change amongst key funders, research organisations.
  - b. **Differing organisational and procedural norms:** Funders and research organizations continue to apply an unwieldy range of research classification systems, making aggregation of research capacity investments difficult. Adoption and use of harmonized protocols and conventions for documenting clinical research projects, research attribution, and syntax for describing specific elements of research activity is still far from optimal. As is the adoption of common standards for the measurement of indicators of

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<sup>15</sup> "By end 2018, WHO should consolidate a robust set of indicators, to the extent possible building on indicators already used by countries, develop a tool for assessment of country-level capacities for clinical research, and propose a process to help countries rapidly conduct these assessments."

<sup>16</sup> The Global Ministerial Forum on Research for Health (2008) The Bamako call to action on research for health: strengthening research for health, development, and equity; Bamako, Mali.

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capacity such as qualified researchers, laboratory quality, ethics, governance and financial management. Differences in other norms such as planning, and budgeting cycles also impact the prospect of effective coordination.

- c. **Competitive and/or political dynamics** – Many funders (private or public) or health research are also actively involved in scientific enquiry which introduces a degree of additional complexity that is a barrier to effective coordination due to direct or tacit competition. Political dynamics between institutions are also a key factor that could make or mar attempts at improving coordination. Indeed, anecdotal evidence suggests that these dynamics have been the single most important factor that have rendered previous attempts at a global coordination mechanism unsuccessful, and existing mechanisms less effective than desired.

#### ***Questions for participants (Section 2.3)***

- *Are the identified barriers to better coordination in clinical research capacity strengthening outlined in this section exhaustive?*
- *What other major gaps that necessitate the idea of a more effective mechanism are missing from the above?*

## **2.4 KEY CONSIDERATIONS FOR THE ENVISAGED MECHANISM: SCOPE & USER NEEDS**

For effective multi-stakeholder deliberation on the envisaged mechanism, all participants need to have a common understanding of the key considerations to be assessed. This section of the paper aims to achieve this by outlining a set of assumptions about the mechanism based on existing literature on the subject and a handful of initial stakeholder interviews. These assumptions are outlined in the following sub-sections as answers to two defining question-sets:

1. What should be the ideal scope of an effective mechanism? What are the key actions envisaged and related components?
2. Who would be the main users of this mechanism? What are their needs and how will they benefit from its existence?

### **2.4.1 Scope considerations for an effective mechanism**

From the preceding section, it is evident that for a mechanism to be effective in this context, it will have to be designed to enable/support **more effective priority setting with respect to investing in clinical research capacity strengthening in LMICs**, within the context of *(and while navigating the inherent pitfalls of)* a **complex institutional landscape**. These two considerations are thus critical in defining the scope of the mechanism.

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Based on stakeholder interviews completed to date in the preparation of this background paper, there appears to be a very high level of interest amongst health research ecosystem actors on better coordination of research capacity building/strengthening activities in LMICs. Whilst there isn't (now) a clear consensus on what the components and key actions of the mechanism should be, the following were suggested as ideal features of such a mechanism:

1. Provide a systematic means to ensure that capacity strengthening priorities for LMICs are identified, and that research capacity investments are aligned with country/national authority priorities and linked to their overall health priorities;
2. Provide access to accurate data on current capacity levels (with emphasis on institutional and national level capacity) in LMIC countries, and the implications for capacity strengthening investments, given the priorities established;
3. Provide access to accurate data on capacity strengthening programs and interventions in LMICs to inform better allocation of resources by funders, and the design of more effective partnerships;
4. Support enhanced direction of resources into clinical research capacity strengthening/building;
5. Provide mechanisms to improve accountability amongst stakeholders to ensure that investments in clinical research capacity building/strengthening are indeed effective





#### ***Questions for participants (Section 2.4.1)***




- *Are the suggested features of an ideal mechanism valid?*
- *What is your perspective on the required actions and key components of an effective mechanism?*

#### **2.4.2 Analysis of user needs and requirements**

Based on literature reviews and stakeholder interviews completed as part of preparing this paper, seven types of stakeholders (in three broad categories) who collectively have needs that an effective mechanism for coordinating investments in clinical research may help address were identified. These stakeholders will be the de-facto 'primary users' of the envisaged mechanism. Brief descriptions of these stakeholders, along with an initial articulation of their needs and desired benefits from the envisaged mechanism are outlined in this section.

Table 1- Analysis of user needs and requirements

Category/Organization	Description	Needs/requirements from mechanism	Envisaged benefits
<b>1 Major public funders of global health research</b> 	<ul style="list-style-type: none"> <li>Private and public global organisations involved with tackling global health challenges by funding the advancement of scientific enquiry in health and biomedical sciences and research capacity strengthening in LMICs. Includes large public and philanthropic and large global biopharmaceutical companies.</li> </ul>	<ul style="list-style-type: none"> <li>Data on ongoing and planned research activity in LMICs</li> <li>Data on ongoing and planned research capacity strengthening investments by national govts, regional devt. organisations and other major funders (researched-linked and non-researched linked)</li> <li>Inclusive, commonly accepted, data on current clinical research capacity by level (individual, institutional and national) and by type of capacity based on an agreed set of metrics and indicators</li> </ul>	<ul style="list-style-type: none"> <li>Better determination of clinical research investment plans and priorities</li> <li>More effective resource allocation</li> <li>Better targeting of capacity strengthening programs to drive improvements at institutional and country levels</li> <li>More insight based strategic partnerships and collaborations</li> <li>Better coordination amongst funders and donors and data driven engagement with LMIC governments</li> </ul>
<b>2 Major private funders of global health research</b> 		<ul style="list-style-type: none"> <li>Inclusive data on current clinical research capacity at LMIC research organizations</li> <li>Site specific research capacity with granular data on: <ul style="list-style-type: none"> <li>Thematic area expertise/experience</li> <li>Scientific training capacity</li> <li>Organizational capacity (financing, governance, lab facilities &amp; infrastructure, quality standards and certifications, ethical standards/procedures)</li> <li>Access to soft infrastructure (e.g. genome data, bioanalysis labs etc)</li> <li>Collaboration &amp; community integration</li> </ul> </li> <li>Quality of national health research infrastructure with emphasis on regulatory capacity for clinical research and clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>Better insights to guide trial design &amp; planning of clinical research with more effective data to guide <ul style="list-style-type: none"> <li>Selection of research/trial sites</li> <li>Sourcing of local PIs and partnerships</li> <li>Budgeting for capacity building programs associated with core research</li> <li>Collaboration with local governments and communities</li> </ul> </li> </ul>
<b>3 Academic research institutes and similar research organizations based in LMICs</b> 	<ul style="list-style-type: none"> <li>Broad range of organisations involved with the direct conduct of biomedical research and health research capacity strengthening in LMICs. Includes LMIC based private and publicly owned academic institutes, and specialist research institutes.</li> </ul>	<ul style="list-style-type: none"> <li>Data on strategic priorities of research funders (private, public and philanthropic) and LMIC governments</li> <li>Standard metrics for assessing institutional capacity</li> <li>Data on institutional capacity strengthening programs and guidance on participation</li> <li>Data on strategic collaboration opportunities</li> </ul>	<ul style="list-style-type: none"> <li>Universally agreed standards upon which to anchor capacity strengthening plans, and interventions</li> <li>External visibility to attract funding and strategic partnerships</li> <li>Promote institutional capacity and capabilities</li> <li>Contribute to scientific knowledge dissemination</li> </ul>
<b>4 International and regional R&amp;D organisations,</b> 	<p>Also includes regional or global, R&amp;D organisations, including product development partnerships, research networks and similar organizations involved with research capacity strengthening as part of collaborative research in LMICs.</p>	<ul style="list-style-type: none"> <li>Data on strategic priorities of research funders (private, public and philanthropic) and LMIC governments</li> <li>Inclusive data on current clinical research capacity at LMIC research organizations</li> <li>Site specific research capacity data with granular information on: <ul style="list-style-type: none"> <li>Thematic area expertise/experience</li> <li>Scientific training capacity</li> <li>Organizational capacity (financing, governance, lab facilities &amp; infrastructure, quality standards and certifications, ethical standards/procedures)</li> <li>Access to soft infrastructure (e.g. genome data, bioanalysis labs etc)</li> <li>Collaboration &amp; community integration</li> </ul> </li> <li>Quality of national health research infrastructure with emphasis on regulatory capacity for clinical research and clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>Insights/evidence to inform capacity strengthening program development and strategic collaboration with other stakeholders</li> <li>Better insights to guide trial design &amp; planning of clinical research with more effective data to guide <ul style="list-style-type: none"> <li>Selection of research/trial sites</li> <li>Sourcing of local PIs and partnerships</li> <li>Budgeting for capacity building programs associated with core research</li> <li>Collaboration with local governments and communities</li> </ul> </li> </ul>

Category/Organization	Description	Needs/requirements from mechanism	Envisaged benefits
<p>5 Governments and Health Governance/Regulatory Authorities in LMICs</p> 	<p>• Organizations that are primarily concerned with promoting demand for health research, facilitating an enabling environment for the conduct of research, mobilizing funding/investments into research, and utilization of research evidence to drive health policy. These includes health policy and regulatory authorities of governments in LMICs, international health governance and regulatory authorities, as well as local and international health research advocacy organisations. .</p>	<ul style="list-style-type: none"> <li>• Data on ongoing and planned research activity in-country (public, private and philanthropic)</li> <li>• Standard metrics for assessing country clinical research capacity for both inter-epidemic research and research during emergency outbreaks</li> <li>• Information on country capacity strengthening programs and collaboration opportunities</li> </ul>	<ul style="list-style-type: none"> <li>• Universally agreed standards upon which to anchor capacity strengthening plans, and interventions</li> <li>• Insights/evidence to inform policy, legislation and regulations to strengthen national health research architecture</li> <li>• Attract funding and strategic partnerships to strengthen national health research capacity</li> </ul>
<p>6 International Health Governance &amp; Regulatory Organisations</p> 		<ul style="list-style-type: none"> <li>• Inclusive data on current clinical research capacity with emphasis country capacity</li> <li>• Standard metrics for assessing country clinical research capacity for both inter-epidemic research and research during emergency outbreaks</li> <li>• Country specific research capacity data with granular information on: <ul style="list-style-type: none"> <li>• <i>Essential national health research plans/priorities; health research regulatory capabilities; clinical research governance (incl. governance of clinical trials); lab facilities &amp; infrastructure</i></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Insights/evidence to inform international health research policy, legislation and regulations to strengthen the global health research systems</li> <li>• Universally agreed standards upon which to anchor international capacity strengthening plans, and country-support interventions</li> </ul>
<p>7 Health/Health Research Advocacy Organizations &amp; CSOs</p> 		<ul style="list-style-type: none"> <li>• Data on ongoing and planned research activity in-country (public, private and philanthropic)</li> <li>• Data on strategic priorities of research funders (private, public and philanthropic) and LMIC governments</li> </ul>	<ul style="list-style-type: none"> <li>• Insights/evidence to inform advocacy campaigns</li> <li>• Ability to better support community engagement programs particularly for clinical research during outbreak/emergency response</li> <li>• Scientific knowledge to inform general public health enlightenment</li> </ul>

**NB: The organization/country logos included in the table below are illustrative examples only and are not exhaustive**

### Questions for participants (Section 2.4.2)

- Are the categories of stakeholders identified in the table above accurate and exhaustive?
- What is your perspective on the needs of each stakeholder group and how these needs differ from one group to the next?

## 3 LANDSCAPE OF CLINICAL RESEARCH CAPACITY & RESEARCH CAPACITY STRENGTHENING IN LMICs

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### 3.1 OVERVIEW

Information provided in the preceding section indicates that there is currently no common mechanism to ensure that research capacity strengthening in LMICs is optimized for greater impact. This section of the paper goes into further detail to describe the prevailing landscape for clinical research capacity and research capacity strengthening in LMICs, by providing secondary data and supporting analysis across two key aspects of the landscape:

- How data on clinical research capacity and research capacity strengthening is currently assessed
- Existing mechanisms for coordinating clinical research investments into LMICs and the extent to which they meet identified needs or address known gaps

### 3.2 ASSESSING CLINICAL RESEARCH CAPACITY/CAPACITY STRENGTHENING: CURRENT LANDSCAPE

#### 3.2.1 Assessing and Indicating Clinical Research Capacity

As earlier indicated, this paper adopts a definition of clinical research capacity that places it along the continuum of health research in general, from a narrow focus on clinical research, to other forms of health research that are critical to effective and efficient health systems. The term ‘capacity’ in this context is to be regarded as ‘a multidimensional concept, which reflects the complex nature of human systems made up of multiple actors interacting with one another in often unpredictable ways<sup>17</sup>. The objective of capacity strengthening efforts being to improve the ability of an individual, organization, sector, or country to not only produce desirable technical results but also to ‘build more effective and dynamic relationships between different actors within a system’<sup>18</sup> in a sustainable way.

There are currently no widely-accepted measures of assessing capacity for clinical research at various levels, neither are there harmonized ratings of research institutions or national health research systems of low- and middle-income countries based on their capacity to undertake clinical research or health research. A few mechanisms that define competencies and/or benchmarks for specific sub-elements of research capacity, or report on capacity assessments are however in use, though with limited scope and uptake. The table below outlines findings with respect to availability of currently applicable mechanisms that indicate (or seek to indicate) research capacity in LMICs.

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<sup>17</sup> Capacity, complexity and consulting: Lessons from managing capacity development projects; 2012 ODI Working paper

<sup>18</sup> Ibid 19



Table 2 – Identified tools for assessing and indicating capacity levels for elements of health/clinical research

<b>Sn</b>	<b>Mechanism</b>	<b>Level</b>	<b>Description</b>
1	The TDR-TGHN Competency Wheel <sup>19</sup>	Individual	Provides a listing of required competencies that should be demonstrated by a research team to carry out a successful clinical study
2	Mapping African Research Ethics Review and Medicines Regulatory Capacity (MARC) <sup>20</sup>	Institutional /National	Map health research oversight and regulatory activities in Africa, collecting data on over 150 African research ethics committees
3	The Laboratory Network Scorecard (LABNET) <sup>21</sup>	National	Scorecard used for the assessment of national laboratory network functionality in Africa. Limited evidence of actual usage though it appears to have been widely promoted at some point.
4	The WHO Global Benchmarking Tool for Regulatory Capacity <sup>22</sup>	National	Assesses and documents capacities of national regulatory agencies, including the capacity to provide informed no-objection to clinical trials, post marketing surveillance and oversight of research during outbreaks
5	WHO Joint External Evaluation (JEE) Mechanism <sup>23</sup>	National	Assesses laboratory and surveillance preparedness for WHO member countries. Voluntary, collaborative, multisectoral process to assess country capacities to prevent, detect and rapidly respond to public health risks whether occurring naturally or due to deliberate or accidental events.
6	Regulatory Information Tracking of Clinical Trials Registration & Ethics Committees (REGTRAC) <sup>24</sup>	National	Part of the International Clinical Trial Platform (ICTRP), the REGTRAC database shows what countries have legislation and regulations on ethics committees and clinical trials registration. Allows the ICTRP to identify the existing supports and barriers, on a government level, for the registration of clinical trials, and in turn, research transparency. Currently publishing data for 27 countries
7	National Health Research Systems (NHRS) Dashboard <sup>25</sup>	National	Part of the Global Observatory for Health R&D, this is a questionnaire-based framework for assessing country capacity to generate scientific knowledge and promote its utilization to improve health and health equity. Consists of four dimensions of health research -

<sup>19</sup> TGHN- The Global Health Network

<sup>20</sup> Established by COHRED in partnership with the South African Research Ethics Training Initiative

<sup>21</sup> More on the LABNET scorecard [https://au.int/sites/default/files/documents/32386-doc-4\\_presentation\\_acdc\\_labnet\\_p\\_ondoa.pdf](https://au.int/sites/default/files/documents/32386-doc-4_presentation_acdc_labnet_p_ondoa.pdf)

<sup>22</sup> More on Global Benchmarking Tool for regulatory Capacity - [https://www.who.int/medicines/regulation/benchmarking\\_tool/en/](https://www.who.int/medicines/regulation/benchmarking_tool/en/)

<sup>23</sup> More on WHO JEE Mechanism here - <https://www.who.int/ihr/procedures/joint-external-evaluations/en/>

<sup>24</sup> More on REGTRAC here <http://apps.who.int/trialsearch/regtrac.aspx>

<sup>25</sup> Policy paper supporting the development of data gathering systems for the NHRS - <https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-015-0054-3>

			governance, creating and sustaining resources, producing and using research, and financing.
8	UNESCO Go-SPIN <sup>26</sup> and UIS Statistics <sup>27</sup>	Individual/National	Provides tools for mapping and analyzing national STI landscape and assessing policies/implementation for more than 50 countries; hosts STI indicators for over 300 countries. UIS Stats collects and reports on information on human resources for scientific research - this information is already accessible through the Global Observatory for Health R&D.
n	<b>Note to participants:</b> Kindly indicate existing tools and mechanisms like the above that are relevant to indicating institutional or national capacity for clinical/health research in LMICs but are not listed.		

### 3.2.2 Assessing Clinical Research Capacity Strengthening Investments

As with clinical research capacity, information on ongoing or planned clinical research capacity strengthening investments in LMICs is not available in a single integrated source. There are instead, multiple sources of data, available based on existing information sharing commitments between private and public funders and research organisations in high income countries (HICs). Most of the data is however tightly linked with scientific research projects being undertaken in LMICs, making it hard to distinguish investments in scientific research from investments in clinical research capacity building/strengthening in a strict sense. Aside from Sub-Saharan Africa, where investments in dedicated capacity strengthening efforts have increased in the past two decades, publicly available data from these sources are stored as actual scientific studies/trials, and grants for various forms of research activity, thus providing limited insights into research capacity strengthening efforts in LMICs of South Asia, East Asia and the Pacific, & Latin American and the Caribbean. Most of the publicly available data is based on previous and ongoing research activity funded by large global funders of health research and the private biomedical industry. Research activities by governments and private actors within LMICs are under-represented in the dominant platforms. Similarly, capacity building/strengthening efforts that are not directly linked to scientific research activity are under-represented.

The table below outlines findings with respect to platforms for inferring data on clinical research capacity strengthening in LMICs.

<sup>26</sup> Link to summary - [https://en.unesco.org/sites/default/files/gospin\\_online\\_platform\\_leaflet\\_en.pdf](https://en.unesco.org/sites/default/files/gospin_online_platform_leaflet_en.pdf)

<sup>27</sup> <http://data.uis.unesco.org/>

<b>Sn</b>	<b>Platform/Host</b>	<b>Description</b>	<b>Level</b>	<b>Source Data</b>
1	The Global Observatory for Health R&D (WHO)	Web based portal, backing a global-level initiative that aims to help identify health R&D priorities based on public health needs, by consolidating, monitoring and analyzing relevant information on the health R&D needs of developing countries; building on existing data collection mechanisms; and supporting coordinated actions on health R&D.	Individual, Institutional & National	Multiple secondary sources; including trial registries
2	World Report (NIH)	Web based interactive platform managed through a steering committee comprising organisations that have agreed to work together to improve data transparency on research investments. Currently includes data reported by 12 major funders of health research. Not all of these funders report on a yearly basis. For example, in 2015 only 9 of the 12 funders reported data (for grants in 2015).	Individual, Institutional & National	Grants, Studies & Trials
3	Health Research Web (COHRED)	Web-based, interactive and growing source of information on the structure and organisation of research for health in and for LMICs. Organised to provide integrated information on research for health at country level and regional level in order to strengthen national health research capability. Users can search by country for information on ongoing health research, health research priorities, and key institutions.	National & Regional	Multiple secondary sources
4	Asia Pacific Observatory for Health Policies and Systems	Online directory of data aimed at improving regional collaboration on health systems policy by providing a single source of data relevant to health systems policy for member countries. The APO collaboratively identifies priority health system issues across the Asia Pacific region, develops and synthesizes relevant research to support and inform countries' evidence-based policy development; and builds country and regional health systems research and evidence-informed policy capacity.	National	Multiple secondary sources
5	WHO International Clinical Trials Registry Portal (ICTRP) & Registry Network	Established following the Ministerial Summit on Health Research in Mexico City in November 2004 as " <i>a network of international clinical trials registers to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others</i> ". The main aim of the WHO ICTRP is to facilitate the prospective registration of the WHO Trial Registration Data Set on all clinical trials, and the public accessibility of that information. <sup>28</sup> The WHO Registry Network provides prospective trial registries with a forum to exchange information and work together to establish best practice for clinical trial registration.	Individual, Institutional & National	Registered Trials
6	ClinicalTrials.Gov (US National Library of Medicine; NIH)	ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical	Individual, Institutional & National	Registered Trials

		study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information on the site is updated throughout the study. In some cases, results of the study are submitted after the study ends. This Web site and database of clinical studies is commonly referred to as a "registry and results database."		
7	Other Trial Registries (Global; Country, & Region-specific Clinical Trial Registries)	Several other registries exist where data on clinical trials are maintained. A number of these countries are part of the WHO Registry Network having obtained recognition by WHO as "Primary Registries". The <b>ICSTRN</b> is a primary clinical trial registry recognized by WHO and ICMJE that accepts all clinical research studies (whether proposed, ongoing or completed), providing content validation and curation and the unique identification number necessary for publication. The <b>Pan African Clinical Trial registry (PACTR)</b> is a recently developed regional registry currently funded by the EDCTP and managed by the South African Cochrane Centre (SACC), an intra-mural research unit of the South African Medical Research Council (MRC).	Individual, Institutional & National	Registered Trials
8	Theme-Specific R&D Databases	A number of platforms for data sharing to aid clinical research capacity strengthening relevant to LMICs, usually hosted by R&D coordination mechanisms for these thematic areas. Examples include the <b>IAVI Clinical Trial Database</b> , hosted by the <b>International AIDS Vaccine Initiative (IAVI)</b> , a nonprofit scientific organization whose mission is to develop vaccines and other biomedical innovations that prevent HIV infection.	Individual, Institutional & National	Registered Trials
9	Academic (scientific) databases & search engines on health & biomedical research	Several platforms exist for finding or accessing articles/publications in academic journals, institutional repositories, archives, or other collections of scientific research. These data sources have hold information that is relevant to LMIC research capacity strengthening. They include <b>Pubmed</b> , a database primarily of references and abstracts on life sciences and biomedical topics; <b>Web of Science</b> , a multidisciplinary portal that includes other products, such as Social Science Citation Index, Science Citation Index, Biological Abstracts & The Zoological Record; <b>ResearchGate</b> , a professional network for scientists and researchers with to share, discover, and discuss research; and other niche platforms such as the <b>Circumpolar Health Bibliographic Database (CHBD)</b> and the <b>Cochrane Library</b> .	Individual	Scientific Publications
10	Country Specific Platforms (CIDACS – FIOCRUZ, Brazil) <sup>29</sup>	The Centre for Integration of Data and Health Knowledge (CIDACS-FIOCRUZ) is to enable studies and research, the development of new investigative methodologies, and the promotion of scientific training, via interdisciplinary projects, and based on the integration of large data bases ("big data").	National	Multiple sources

<sup>28</sup> <https://www.who.int/ictrp/about/en/>

<sup>29</sup> More about CIDAC FIOCRUZ <https://cidacs.bahia.fiocruz.br/en/>

11	Financial Tracking Platforms (G-FINDER <sup>30</sup> , RESIN <sup>31</sup> , IHME <sup>32</sup> )	G-FINDER (2008–present) The G-FINDER project publishes reports on global investment into neglected disease R&D and maintains a public database of such investments. The Institute for Health Metrics and Evaluation undertakes a Financing Global Health (FGH) study (2009–present). The study reports on trends in development assistance for health, as well as other health spending, and provides a public database of spending data. The Research Investments in Global Health (ResIn) study is an analysis of global investments in health research and is based at the University of Southampton. RESIN was awarded funding from the Bill & Melinda Gates Foundation to cover infectious disease research investment analyses across the G20 countries, with a particular focus on the investment portfolios relating to pneumonia, neonatal infectious disease and maternal immunization <sup>33</sup> .	National	Funding flows
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Table 3- Platforms with data relevant to clinical/health research capacity strengthening in LMICs

<sup>30</sup> More about G-FINDER here <http://www.policycures.org/gfinder.html>

<sup>31</sup> More about RESIN here: <http://researchinvestments.org/>

<sup>32</sup> IHME FGH Study visualization data can be found here: <https://vizhub.healthdata.org/fgh/>

<sup>33</sup> Ibid 33

### 3.3 INVENTORY/REVIEW OF EXISTING MECHANISMS FOR IMPROVING COORDINATION

The landscape for research capacity strengthening for LMICs is broad and highly fragmented, with several mechanisms in existence aimed at enhancing synergy, coordination and effectiveness of investments in clinical research in developing countries. This section of the paper aims to provide an inventory of these mechanisms (more details provided in the appendix) and review their scope vis-à-vis the scope of what could be envisaged as an effective mechanism, as established in Section 2.4.1 based on stakeholder interviews completed in the preparation of this background paper. An attempt is also made to provide a perspective on how they are positioned vis-à-vis a set of key factors related to institutional complexity, which was established in Section 2.3 as a major barrier to improving coordination.

A few key points are noteworthy in relation to the summary of findings on the inventory of mechanisms reflected in the table below.

- The term ‘mechanism’ is used to refer to any initiative set-up or embarked upon with the objective of improving synergy, between and among multiple organisations involved with any aspect of research capacity strengthening, with the potential to impact national research systems in LMICs. Note that emphasis here is placed on the primacy of capacity strengthening in the mandate of the initiative, as against, for example the development of new products. The list provided below also focuses on mechanisms that are multi-dimensional in terms of the aspects of coordination that they are involved with. This explains the omission of predominantly data sharing platforms (already profiled) from the list below, without prejudice to the fact that these platforms are indeed coordination mechanisms, given the widely acknowledged centrality of data sharing and information symmetry to health research coordination.
  - Available mechanisms are organized in several ways: by specific disease, by broad area of disease by product (e.g. vaccines), or by region. Many initiatives are cross-cutting in nature, seeking to improve coordination at the level of national or international health policy. The list of mechanisms indicated below is inclusive of all the available categories.
  - The factors under *Scope* are explained in Section 2.4.1
  - The factors under *Institutional complexity* are explained as follows:
    - i. Institutional remit – the extent to which the mechanism’s primary remit enables it to work on LMIC priorities as against other areas of clinical research/capacity strengthening
    - ii. Degree of influence – the extent to which the mechanism can influence participating organizations to adapt their internal systems and/or procedures to align with decisions collectively reached
    - iii. Neutrality – The extent to which the mechanism is (or perceived as) free of controlling influence by one (or a subset of) participants
-

	Scope					Institutional Complexity		
	Strategic Alignment	Information Sharing - Capacity	Information Sharing - RCS	Resource Allocation	Accountability	Institutional Remit	Deg. of Influence	Neutrality
TDR								
ESSENCE								
Global AMR R&D Hub								
Global Alliance on Chronic Diseases								
UKCDR								
Pan American Health Org.								
West Afr. Health Org.								
European & Dev. Countries CT Partnerships (EDCTP)								
Joint Programming Initiative on AMR								
Intl. Federation of Pharma Manufacturers & Associations								
Product Devt. Partnerships Funders Forum								
Program of R&D in Human Reproduction (HPR)								
Global Coordination Mechanism on R&D Blueprint								
Institute Pasteur								
Coalition for Epidemic Preparedness Innovations								
India Alliance								
African Network for Drugs & Diagnostics Innovation (ANDI)								
South Asian Forum for Health Research								
Alliance for Health Policy and Systems Research (AHPSR)								
International Forum for Research Donors (IFORD)								
AAS/Alliance for Accelerating Excellence in Science in Africa								
Council on Health Research for Development (COHRED)								

Heads of Intl. Research Organizations (HIROS)								
Southeast Asia Influenza Clinical Research Network								
Multiple Product Devt Partnerships (PDPs)								

**Legend:** Green: Applicable/Strong; Amber: Not Applicable/Weak; Blank: WIP

Table 4 - Existing mechanisms and their key attributes

**Note to participants:**

- The mapping in the table below is merely indicative of the organizational character of these mechanism based on limited publicly available information only. Based on your personal knowledge or experience interacting with the organizations above, please validate the above characterization of these mechanisms in terms of their scope and standing; and prepare to share your perspectives as necessary to enrich the deliberations during the consultation session.*



### 3.4 SYNTHESIS OF KEY FINDINGS ON THE LANDSCAPE REVIEW

This section attempts an initial synthesis of the key findings from the landscape review presented in the preceding sections.

#### *Key elements of the current landscape and their potential implications for mechanism design*

The landscape for assessing clinical research capacity and investing in clinical research capacity strengthening in LMICs is complex, given the diversity of actors and the differences at national and regional level. From the perspective of improving coordination, we highlight three defining elements:

1. *Absence of strong nationally-owned systems for assessing/evaluating clinical/health research capacity and sharing the results of such assessments.*

There is little evidence that LMIC governments' have systems in place to assess clinical/health research capacity especially at the institutional or national level. Many developing countries, are yet to properly prioritize health research capacity as part of development policy. As a result, the landscape review shows that strong nationally-owned and driven systems for assessing clinical/health research capacity are not common. In the absence of national systems, several regional systems exist in which these countries participate, mostly under the auspices of the WHO. These systems tend to be theme specific, e.g. the WHO Global Benchmarking Tool for Regulatory Capacity measures provides a framework for measuring national regulatory capacities for medicines and vaccines, while the Africa-specific Laboratory Network (LABNET) does same for laboratory network capacity. Adoption and use of these frameworks are still at an infancy stage, and the expectations is that these will lead to more country-generated data on clinical/health research capacity in LMICs. The design of an effective coordination mechanism should consider ways to **improve the definition of competencies and standards that reflect capacity**, and ways to **encourage usage and uptake of assessment frameworks by LMICs**, to **increase the availability of quality country-generated data on prevailing capacity** and **simplify gap analysis/intervention design**.

2. *Use of multiple, discrete externally designed systems to assess clinical/health research capacity and/or review research capacity strengthening investments in LMICs without sufficient alignment in objectives and data sets used to inform such assessments/reviews.*

Structural gaps in the availability of data from country-based systems have led to a situation where there is currently no universally acceptable, singular data source on clinical research capacity for low- and middle-income countries. As a result, key actors in the health research ecosystem rely primarily on proxy data, which is largely anchored on the volume of previous and/or ongoing research activity per country in the form of studies, clinical trials and research grants, being funded by similar actors.

The challenge with this approach is that different actors in the health research ecosystem have varying needs for information on clinical research capacity and have therefore adopted different approaches to sourcing data on clinical research capacity. This has led to significant information

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asymmetry and the absence of a unified lens for assessing capacity issues and reaching harmonious decisions that strengthen research capacity in low- and middle-income countries (LMICs). Consequently, resource capacity considerations for LMICs are not informed by accurate and consistent set of data. For example, high volume of research activity in one institution or country relative to another may or may not indicate a higher level of expertise in one organisation, and often does not yield any further insights that could inform the design of an effective capacity strengthening intervention for the benefit of the purportedly 'weaker' institution.

Despite the above, there is recognition that better data transparency on clinical research investments, even if based on proxy data generated by large funders could be transformative. Along this line of thinking mechanisms like the World Report, the Global Health Observatory and Clinical Trial Registries have emerged to increase the level of data transparency amongst large funders of health research, but issues remain with the value of the data available:

- *Utility value of existing data is sometimes skewed to individual researchers and public funders alone, and not easy to use by other ecosystem actors (e.g. limited availability/sharing of site-specific capacity needed by private funders).*
- *Existing data is too simplistic, and unable to provide an acceptable appraisal of institutional and country clinical research capacity – data on aspects of capacity such as regulatory, ethical review, human resources, laboratory quality, community engagement data particularly limited are not typically integrated into these platforms*
- *Data quality issues persist across multiple platforms due to differences in data storage protocols, affecting the completeness and validity of the data*
- *Available data is not sufficiently predictive value-positive, and not primarily designed to support a forward-looking perspective*

Key considerations relevant to this issue include how to address the complexity question, given that data-sharing systems that are designed to meet the needs of all stakeholders run the risk of being either **too simple to satisfactorily address needs or becoming too complex to be efficiently and cost-effectively maintained** and kept relevant. Finding the **right-subset of stakeholder needs that can be met to create the most impact** and the **right subset of data to optimize and make more meaningful** will be crucial. Also critical is designing the **right format for the presentation of data to maximize its utility**. Optimal use of **leading-edge visualization technologies** will be key to success.

3. *Absence of organizations/entities that have a broad enough remit to lead/drive a holistic approach to coordination, yet structurally and functionally simple enough to navigate the institutional complexities inherent in the landscape*

Given the institutional complexities previously described, deciding on the organizational entity within which this mechanism should be embedded, and resolving important questions of how it is governed and funded without **negatively impacting its LMIC focus, organizational agility and responsiveness, and political neutrality are important design considerations**. Achieving collective accountability amongst participating organisations in a way that is non-threatening yet effective, will be critical to success.

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***Questions for participants (Section 3.4)***

- *This section synthesizes the landscape analysis into three (3) defining elements and highlights their respective implications for designing a more effective mechanism. What are your thoughts on this?*
  - *What other aspects of the landscape should influence how we think about designing the envisaged mechanism?*
  - *What kind of mechanism is likely to provide further incentives for investments in capacity building in countries that are especially weak?*
-

## 4 COORDINATION MECHANISMS: ALTERNATIVE MODELS AND OPTIONS TO CONSIDER

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### 4.1 OVERVIEW

The preceding sections of this paper outline the current landscape for clinical research capacity and clinical research capacity strengthening in LMICs, highlights several prevailing issues, and an initial examination of the potential implications for the design of an effective mechanism. This section of the paper delves further into the topic of mechanism design, by examining a few potentially useful case studies.

### 4.2 CASE STUDIES: MODELS & MECHANISMS FOR IMPROVING COORDINATION

The case studies provided in this section were selected based on their potential usefulness in **providing a broad set of insights** that are relevant to three key design expectations of the envisaged mechanism:

1. **Higher levels of data accuracy:** More accurate representation of research capacity based on real-time/near real-time verifiable on-the-ground (bottom-up) data, preferably from nationally-owned or managed assessment systems, using an inclusive set of pre-agreed standards and metrics, as against the wide use of ineffectual/misleading proxy data
2. **Effective data aggregation and sharing:** Higher levels of data availability and data transparency on clinical research capacity (*per pt. 1 above*), and ongoing/planned clinical research capacity strengthening investments; to inform decision making on priority setting, resource allocation and investment coordination
3. **Sustainability:** Greater prospects of sustained participation and support due to suitability and ease of use by multiple institutions, regardless of institutional complexities and differences between them

#### 4.2.1 Case Study #1: The CGIAR Platform for Big Data in Agriculture

The CGIAR Platform for Big Data in Agriculture<sup>34</sup> is one of three *research support platforms* which underpin and enable the research of the entire the CGIAR system. The other two platforms are the *Excellence in Breeding Platform*, which aims to become the one-stop place to go for advice, tested resources and best practices for any breeding program targeting the developing world; and the *CGIAR Genebank Platform*, which monitors, test, germinate, multiply, characterize, clean, culture, store, and distribute germplasm under high scientific standards of operation, and deals with individual requests for crop diversity from users worldwide as well as within the CGIAR<sup>35</sup>.

The goal of the platform is to **harness the capabilities of Big Data to accelerate and enhance the impact of international agricultural research**. The Platform is expected to achieve this through partnerships with

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<sup>34</sup> CGIAR Big Data Coordination Platform Leveraging CGIAR data: Bringing big data to agriculture, and agriculture to big data; being the Big Data Coordination Platform: Full Proposal 2017-2022; CGIAR; 2016

<sup>35</sup> For more information, visit <https://www.cgiar.org/research/program-platform/genebank-platform/> and <https://www.cgiar.org/research/program-platform/excellence-in-breeding-platform/>

initiatives and organizations outside CGIAR, both upstream and downstream, public and private. It will focus on promoting CGIAR-wide collaboration amongst its research centers, in addition to developing new partnership models with big data leaders globally. The Platform has three core objectives:

1. **Organize:** Support and improve data generation, access, and management across the CGIAR system
2. **Convene:** Collaborate and convene globally around big data and agricultural development, providing opportunities and spaces for facilitated virtual collaboration and interaction among partners and stakeholders, and hosting a Big Data Convention to drive bring key actors to CGIAR and vice-versa
3. **Inspire:** To lead by example and inspire the research community on how big data can deliver development outcomes, through inspirational projects that solve development challenges

The strategic plan underpinning the platform recognizes that as a first and necessary step, CGIAR must get its own house in order with respect to data. Hence it prioritized the three objectives in sequence, with objective #1 focused on acquiring the infrastructure, tools and data culture to succeed, in both technical and managerial dimensions. The minimum success factor for this objective is compliance with the open access and open data policy of CGIAR, ensuring donors and investors in CGIAR can be confident that data is being managed and shared effectively across all CGIAR operations.

The “Organize” module of the platform drives the execution of objective #1, by building capacity throughout CGIAR to generate and manage big data, assisting CGIAR and its partners’ efforts to comply with open access/open data principles to unlock important research and datasets<sup>36</sup>. The following focus areas of its work are particularly noteworthy:

1. Establishing a process, supporting compliance, and enabling a data culture in alignment with the **CGIAR Open Access and Data Management (OADM) Policy**<sup>37</sup>.
2. Investing in an **online tool (Global Agriculture Research Data Innovation and Acceleration Network (GARDIAN))**<sup>38</sup> that enables users to easily search and discover open datasets and publications across databases at all CGIAR Centers, with the intention of making this a key mechanism for monitoring and measuring compliance with the CGIAR open access policy.
3. Executing the mandate to of the platform to produce international public goods and ensure that these are open via **FAIR** principles – that is, the data are **Findable, Accessible, Interoperable and Reusable**. This enables the data to be used to enhance innovation, impact, and uptake.
4. Supporting data managers at research centers with a **Data Management Support Pack**<sup>39</sup>. This tool was designed to help the research community produce high quality, reusable, and open data from research activities. It consists of **documents, templates, and videos covering a range of aspects related to data management and interoperability**, ranging from overarching concepts and strategies through to day-to-day activities. Also runs a monthly webinar series to support the **management and “FAIRification”** of information resources.

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<sup>36</sup> Information directly referenced from <https://bigdata.cgiar.org/organize/>

<sup>37</sup> Ref: <https://www.cgiar.org/how-we-work/accountability/open-access/>

<sup>38</sup> <http://gardian.bigdata.cgiar.org/#1/>

<sup>39</sup> More information on the data management support pack can be found here: <https://ccafs.cgiar.org/data-management-support-pack>

5. Developing data privacy and ethics guidelines to ensure that data sharing and use comply with ethical standards that protect those who could be vulnerable to exploitation
6. Investing in learning and capacity building initiatives to accelerate data sharing as well as key analytic capabilities across the CGIAR via multiple means, to encourage increased investment in developing data repositories and software infrastructure to build open data sharing and storage capabilities; and investment in new staff roles for data curation, collection, and analysis.

**Leadership, management and governance:** The Platform is designed to be co-led by two of its research centers with the strongest track record for data-driven research - CIAT and IFPRI - with both Centers sharing responsibility for the Platform to deliver. Leadership is provided through a lean Secretariat, to consist of a Big Data Coordinator, a communication and engagement specialist, and modest administrative support. The estimated annual budget for the secretariat is US\$250k. An Executive Management Team is envisaged to meet bimonthly to actively manage the Platform, and a Steering Committee (SC) is proposed to provide oversight and direction, formally reporting to the CIAT Board, given that CIAT is the signatory to the performance contract with the CGIAR System Office and has overall fiduciary and operational responsibility for the Platform. The cost of the SC is estimated to be <\$20,000 per year. An International Advisory Board (IAB) will also be set up, and will meet face-to-face once per year, and virtually once per year, to explicitly examine how the CGIAR Platform on Big Data connects effectively with other global and regional efforts.

#### 4.2.2 Case Study #2: The UN Office of the Coordination of Humanitarian Affairs (UN: OCHA)

The OCHA is the part of the United Nations Secretariat responsible for bringing together humanitarian actors to ensure a coherent response to emergencies. OCHA also ensures there is a framework within which each actor can contribute to the overall response effort. OCHA's mandate stems from General Assembly (GA) resolution 46/182 of December 1991, which states: "The leadership role of the Secretary-General is critical and must be strengthened to ensure better preparation for, as well as rapid and coherent response to, natural disasters and other emergencies." To this end, it also establishes the role of the Emergency Relief Coordinator (ERC), who works with the Secretary-General and the Inter-Agency Standing Committee (IASC) in leading, coordinating and facilitating humanitarian assistance. OCHA is the office that provides support to the ERC and the Secretary-General to meet the leadership and coordination responsibilities charted in GA resolution 46/182.

OCHA coordinates humanitarian action to ensure crisis-affected people receive the assistance and protection they need. It works to overcome obstacles that impede humanitarian assistance from reaching people affected by crises, and it provides leadership in mobilizing assistance and resources on behalf of the humanitarian system. It is not an operational agency directly engaged in the delivery of humanitarian programs, and its added value is as an honest broker, facilitator, thought leader and global advocate, providing support to the humanitarian system. In fulfilling its coordination mandate, OCHA is guided by the humanitarian principles of humanity, neutrality, impartiality and independence. OCHA is also guided by a number of noteworthy principles:

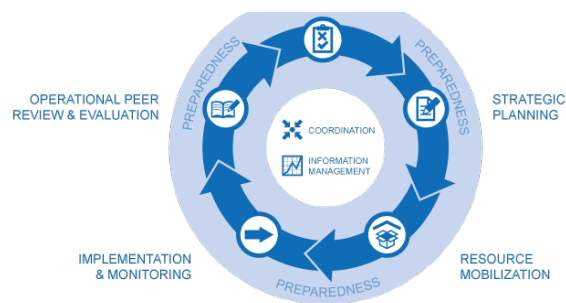
- Diversity – ensures that all stakeholders have a role in saving and protecting lives and alleviating human suffering by promoting coordination mechanisms and processes that are open for participation to all relevant local and global humanitarian actors.
-

- **Trust** - Believes that mutual trust is the foundation for successful partnerships, hence its non-programmatic coordination role enables it to fulfil its unique function as an honest broker.
- **National and local ownership** - Works in full recognition that Member States retain the primary responsibility for the provision and coordination of humanitarian aid to affected populations. Hence it focuses on augmenting national and local coordination capacities yet staying guided foremost by the interests of people who need humanitarian assistance.

OCHA, working with its partners, contributes to effective humanitarian response through five key functions, with coordination and information management at the core of its operational framework for effective coordination (Ref fig 5 below)

1. **Coordination** - to expand the reach of humanitarian action, improve prioritization and reduce duplication
2. **Humanitarian Financing** – to mobilize and engage the full range of financing instruments, mechanisms and partners to ensure that growing humanitarian needs are met
3. **Advocacy** - raises awareness of forgotten crises, promotes respect for international humanitarian law (IHL), and brings the voices of crisis-affected people to the forefront
4. **Policy** – to set the agenda for humanitarian sector reform and effectiveness in response to changes in the global landscape, and to increase capacities of national Governments and local actors
5. **Information management** - provides information management services to the humanitarian community to inform an effective response, by gathering, sharing and using data and information, to underpin coordination, decision-making and advocacy

Figure 1- OCHA Humanitarian Programme Lifecycle

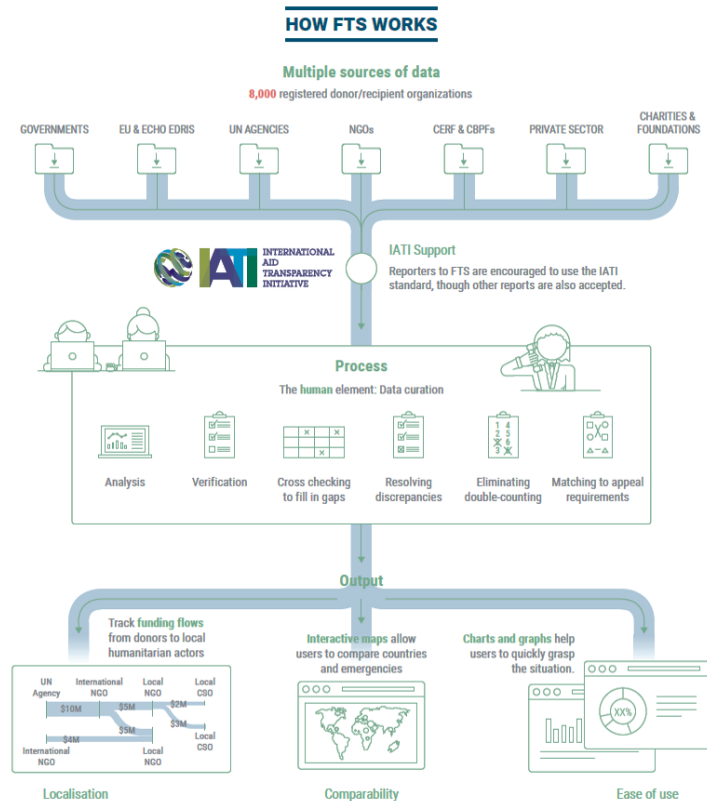


For the purposes of this background paper, the following focus areas of OCHA's work are particularly noteworthy:

- **Backbone for various coordination mechanisms:** OCHA serves as the secretariat for critical inter-agency coordination mechanisms related to humanitarian assistance such as the Inter-Agency Standing Committee, rapid-response tools, such as the United Nations Disaster Assessment and Coordination system, and the International Search and Rescue Advisory Group. This role allows OCHA to draw upon its experience to affect a number of key **processes and procedures** through which humanitarian response capacity building, response preparedness, and response coordination efforts are executed.

- Financial Tracking Service:** OCHA runs and manages the Financial Tracking Service, which aims to present a complete picture of all international humanitarian funding flows, collating data on humanitarian funding flows submitted by Government donors, UN-administered funds, UN agencies, NGOs and other humanitarian actors and partners, including the private sector. It verifies and combines these reports using a consistent methodology, ensuring that data is fully comparable and presented as a seamless whole. The FTS is continuously updated and provides visibility on financial contributions to humanitarian activities, flows between donors and recipient organizations, and timely monitoring of funding progress against humanitarian response plan and appeal requirements. This service supports the transparency and accountability of the humanitarian system and facilitates resource mobilisation: it informs real-time decision-making at both national and global levels across all humanitarian emergencies and actors, focusing not just on contributions but also on the allocation and use of funds. Though based on a voluntary reporting mechanism, reporters of data to the FTS are encouraged to align with the *International Aid Transparency Initiative*<sup>40</sup> standard. An illustration of the FTS workflow is provided in Fig 6.

Figure 2 - How the FTS Works



- The Humanitarian Data Exchange (HDX)**<sup>41</sup>: The HDX is an open platform for sharing data across crises and organisations. Launched in July 2014, its goal is to make humanitarian data easy to find and use for analysis. It is Managed by OCHA's dedicated *Centre for Humanitarian Data*<sup>42</sup>, which is in The Hague. The HDX team includes OCHA staff and several consultants who are based in North America, Europe and Africa. The Centre is focused on increasing the use and impact of data in the humanitarian sector and its desired outcomes include: speeding-up the flow of data from collection to use and ensuring greater real-time value of data; optimizing access to shared data infrastructure; and ensure that data is used better and more often by the people who are making critical decisions in a humanitarian response. The Centre's software and standards are open

<sup>40</sup> More information about the International Aid Transparency Initiative Standard can be accessed at <https://iatistandard.org/en/iati-standard/>

<sup>41</sup> More information about the Humanitarian Data Exchange can be accessed at <https://data.humdata.org/faq>

<sup>42</sup> More information about the Centre for Humanitarian Data can be accessed at <https://centre.humdata.org/>



source with all code made available through GitHub<sup>43</sup>. In addition to the HDX, the Centre also manages the Humanitarian Exchange Language (HXL), a data standard to help ease data exchange and improve the analytic value of data.

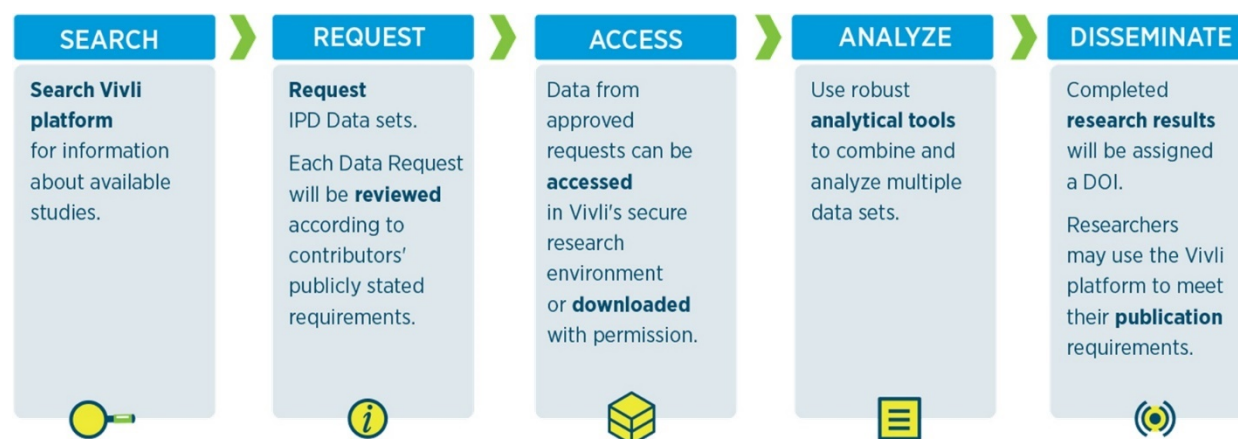
**Financing & Budget:** OCHA is reliant on voluntary contributions from Member States, the European Commission, and other donors for its funding, as only 5 per cent of its annual budget is funded from the United Nations Regular Budget. OCHA’s 2018 extra budgetary (XB) opening budget was \$240.8 million, representing a decrease of \$34 million, or 12 per cent compared with the 2017 opening budget of \$274.8 million. OCHA’s administrative budget is funded by program support costs levied on the XB at 7 per cent (**approx. \$16.85m for 2018**).

#### 4.2.3 Case Study #3: Vivli – The Center for Global Clinical Research Data

Vivli is an independent, non-profit organization that has developed a global data-sharing and analytics platform which focuses on sharing **individual participant-level data from completed clinical trials** to serve the international research community. Its stated mission is “to promote, coordinate, and facilitate scientific sharing and reuse of clinical research data through the creation and implementation of a sustainable global data-sharing enterprise....act as a neutral broker between data contributor, data user and the wider data sharing community”. Vivli evolved from a project of *The Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center)*<sup>44</sup> to enhance access to clinical trials data by promoting data sharing and transparency.

The Vivli platform includes an independent **data repository, an in-depth search engine and a secure research environment**. Its platform process is illustrated in Fig 7 below.

Figure 3- Vivli Platform Process



Data sharing on the Vivli platform is linked to membership, requiring a signed Data Contributor Agreement and a signed Vivli Data Use Agreement. The data package includes protocol, anonymized individual participant-level dataset, data dictionary, and statistical analysis plan at a minimum; with additional elements such as annotated case report forms, clinical study report, and analysis ready datasets are

<sup>43</sup> Refer to <https://github.com/OCHA-DAP>

<sup>44</sup> Find more information at <https://mrctcenter.org/>

optional. Anonymization of the data is offered as a paid service, as with storage and review by an independent review panel.

Vivli is operated as a non-profit organization and is currently funded by a four charitable foundations/trusts and the Pharmaceutical Research and Manufacturers of America (PhRMA). Its model is founded on several strategic partnerships, and its strategic partners are Microsoft (core platform technology provider), Ropes & Gray (corporate, regulatory and IP counsel), Privacy Analytics (data security and anonymization), Wellcome Trust (Independent Review Panel), Cochrane (expertise for synthesis of research evidence), and DataCite (digital identifiers for scientific studies).

#### 4.2.4 Comparing the three models reflected in the case studies

The case studies presented in the preceding sections highlight three markedly different approaches to improving coordination between multiple stakeholders in contexts where data governance, transparency and sharing is central to successful coordination. Table 2 below attempts to compare the three models, vis-à-vis the earlier highlighted design principles of the envisaged mechanism:

*Table 5- Key attributes of each model*

	<i>Higher levels of data accuracy</i>	<i>Effective data aggregation and sharing</i>	<i>Sustainability</i>
<i>Case Study #1: CGIAR Big Data Platform</i>	<ul style="list-style-type: none"> <li>▪ High emphasis on quality of data to support advanced analytics</li> <li>▪ Emphasis on data collection/storage infrastructure and analytic capabilities at source (research institutions/centers)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Promotion of common standards (Open/Access/Open Data policy)</li> <li>▪ Promotion of common principles (FAIR Principles)</li> <li>▪ Technical support for data managers (Open Data Management Pack)</li> <li>▪ Use of integrated search platform (GARDIAN)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Lean management and governance structure</li> <li>▪ Fiduciary and operational responsibility residing in a single research centre</li> </ul>
<i>Case Study #2: United Nations: OCHA</i>	<ul style="list-style-type: none"> <li>▪ Clear distinction between data on financial flows (FTS) and data on humanitarian projects (HDX)</li> <li>▪ Bottom up (country-led) process for identifying funding requirements</li> <li>▪ Centralized entity responsible for curation</li> </ul>	<ul style="list-style-type: none"> <li>▪ Use of open source technology and common platform (HDX)</li> <li>▪ Promotion of common standards (IATI)</li> <li>▪ Promotion of common syntax for data documentation (HXL)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Dedicated centre for humanitarian data (distinct from financial tracking service)</li> <li>▪ Lean management and governance structure</li> </ul>

	and triangulation of data from multiple sources		
<i>Case Study #3: Vivli Centre for Clinical Research Data</i>	<ul style="list-style-type: none"> <li>▪ High levels of data quality control at the point of data contribution</li> </ul>	<ul style="list-style-type: none"> <li>▪ Use of enforced agreements on data use and tightly pre-defined data packages and datasets</li> </ul>	<ul style="list-style-type: none"> <li>▪ <i>Data not available</i></li> </ul>

#### ***Questions for participants (Section 4)***

- *What lessons can we glean from the above case studies that are applicable to designing a mechanism for better coordination of clinical/health research capacity strengthening in LMICs?*
- *What other models do you reckon we can learn from? (please prepare points that can be shared during general discussion at the March 2019 consultation)*

## 5 RECOMMENDING A MORE EFFECTIVE MECHANISM: GUIDING PRINCIPLES AND STRATEGIC FRAMEWORK

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### 5.1 OVERVIEW AND GUIDING PRINCIPLES

Effective deliberations to recommend a better mechanism for improving coordination will require stakeholder alignment around the desired end state that the mechanism is expected to bring about, and agreement on a set of guiding principles. This section of the paper proposes language on the above for consideration, and lays out a framework to guide the development of recommendations at the March consultation.

***Desired end-state that the mechanism should bring about (proposed language for review at the March 2019 consultation):***

*‘The primary objective of the envisaged mechanism is to optimize accuracy, transparency and availability of data on clinical/health research capacity and research capacity strengthening in LMICs, to expand the scale and reach of investments, improve prioritization, and reduce duplication, ensuring the emergence of national health research systems that can meet the needs of their respective populations’*

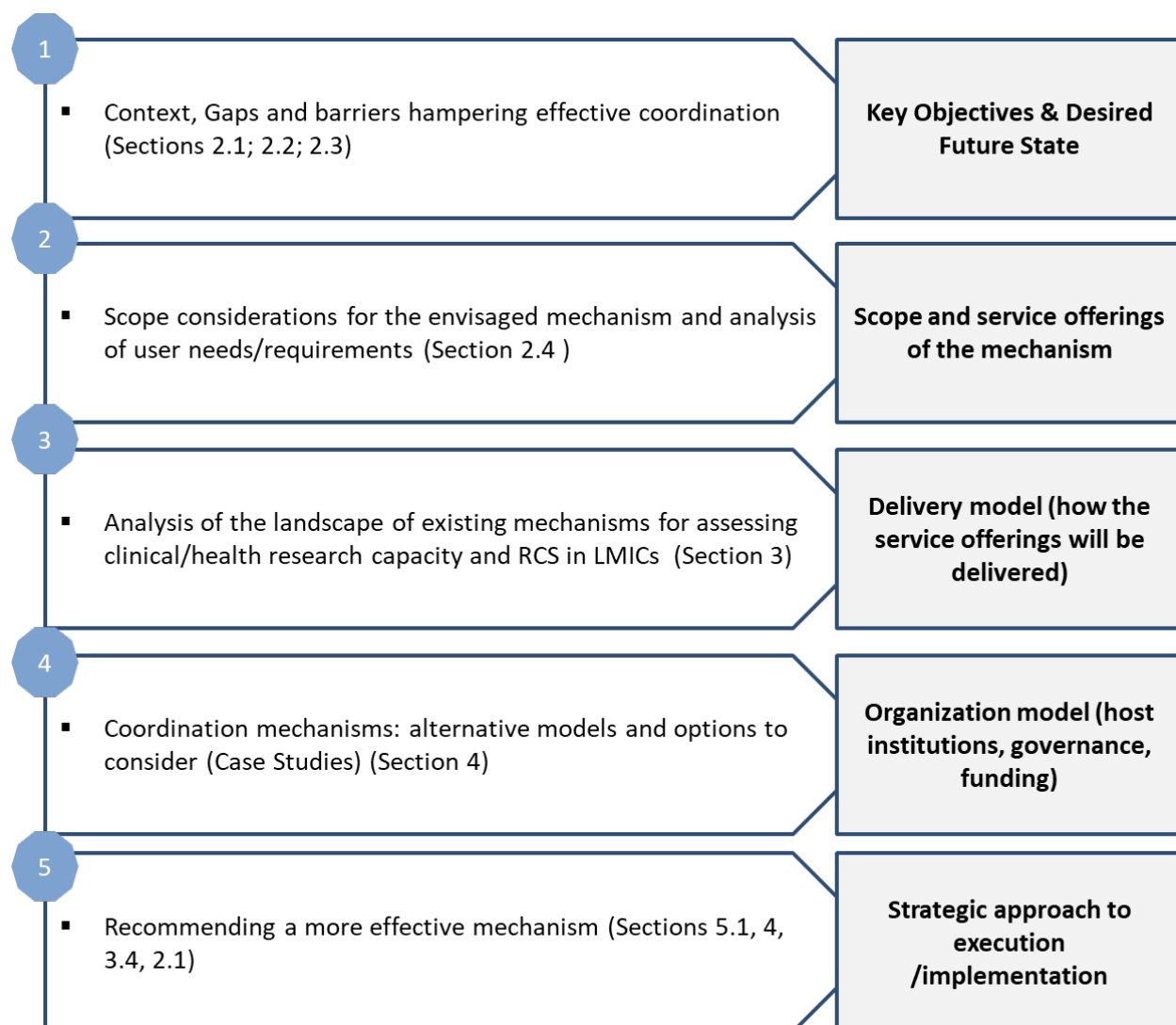
***Guiding principles for designing the envisaged mechanism:***

1. **A journey, not a destination:** Optimizing data accuracy, transparency and availability to improve coordination on research capacity strengthening should be regarded as a journey, and not a destination. Decisions on objectives, scope, and outputs for the mechanism must therefore be considered across the long-, medium-, and short-term, with appropriate emphasis given to getting the sequencing right and resolving interdependencies. In addition, principles, standards, and procedures, should be defined to serve the long-term interests of the scientific community.
  2. **Modular thinking and portable milestones:** The diversity of stakeholder needs and expectations from a mechanism, coupled with the limited success of previous attempts necessitates an approach to design that focuses on achieving recognizable early results efficiently and cost-effectively for a critical sub-set of stakeholders.
  3. **Avoiding potential landmines:** The design of the mechanism must take due cognizance of the institutional complexities in the landscape, which pose a significant risk to the success of any mechanism if not properly considered. Stakeholders must be willing to think beyond conventional norms in allocating responsibility/accountability for various aspects of the envisaged mechanism amongst different actors.
-

## 5.2 PROPOSED FRAMEWORK FOR CONSIDERING OPTIONS & ALTERNATIVES

This section of the paper provides a practical guide for using the information provided and referenced throughout the background paper to inform participant preparation ahead of the March 2019 consultation session and enable efficient deliberations at the session proper.

Figure 4 - Framework to guide use of the background paper for preparation



Based on the above framework, a deliberation/output worksheet that could be useful at the session is provided below, along with an illustrative framework for the consideration of strategic options and alternatives with respect to the envisaged mechanism that may be useful in discussions related to the scope and service offerings, delivery model(s) and organization model (s).

Figure 5- Deliberation/output worksheet (proposal, subject to modification)

Why	<div>1</div> <b>Key Objectives &amp; Desired Future State</b>	
What	<div>2</div> <b>Scope and service offerings of the mechanism</b>	<div>3</div> <b>Delivery model (how the service offerings will be delivered)</b>
		<div>4</div> <b>Organization model (host institution(s), governance, funding)</b>
How	<div>5</div> <b>Strategic approach to execution /implementation (consultation procedures, road map. work plan, RACI matrix)</b>	

Table 6- Illustrative framework for the consideration of alternatives

	1	2	3	4	5	?
Requirements	Investment Tracking & Analytics Service	Institutional & National Health Research Capacity Standards	Institutional & National Health Research Capacity Dashboard	Quality Clinical Trial Site Support Service	Big Data Platform for Clinical Research	?
<b>Description/ Objective</b>	<ul style="list-style-type: none"> <li>Strictly for tracking and visualizing investment flow into LMIC clinical research/research capacity building by large global funders</li> </ul>	<ul style="list-style-type: none"> <li>Definition and management of standards for bottom up assessment of institutional and national research capacities</li> </ul>	<ul style="list-style-type: none"> <li>Strictly for visualizing and reporting on country-led capacity assessments based on the standards defined and maintained by the WHO (Ref 2)</li> </ul>	<ul style="list-style-type: none"> <li>Strictly for sharing verified site level data that enables research organizations to evaluate site-level readiness for clinical trials and determine detailed capacity building investments required</li> </ul>	<ul style="list-style-type: none"> <li>Optimization of available data across clinical trial registries to increase their suitability for advanced analytics and their overall value and usability</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>
<b>Primary Users/ Beneficiaries</b>	<ul style="list-style-type: none"> <li>Large global health donors</li> <li>LMIC Health Authorities</li> </ul>	<ul style="list-style-type: none"> <li>LMIC research institutions</li> <li>LMIC health Authorities</li> <li>Global health Authorities</li> </ul>	<ul style="list-style-type: none"> <li>All health research stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>Private industry</li> <li>International research organizations</li> <li>CROs</li> </ul>	<ul style="list-style-type: none"> <li>Researchers</li> <li>Research organizations</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>
<b>Delivery model</b>	<ul style="list-style-type: none"> <li>Adoption of common research reporting/financial mgt. software by all institutes supported by participating funders</li> <li>Technology enabled dedicated data management and analytics team</li> </ul>	<ul style="list-style-type: none"> <li>Review, publishing and maintenance of competencies and standards for assessing capacity at institutional and country level</li> </ul>	<ul style="list-style-type: none"> <li>Data aggregation platform supported by dedicated data management and analytics team</li> </ul>	<ul style="list-style-type: none"> <li>Encourage the emergence of clinical trial 'broker' organisations who work with trial sites in LMICs to assess readiness, and recommend site-level capacity investments</li> <li>Data sharing platform</li> </ul>	<ul style="list-style-type: none"> <li>Adoption of common open access and open data management standards for clinical research</li> <li>Data aggregation and analytics platform (like GARDIAN<sup>45</sup>)</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>
<b>Host organization</b>	<ul style="list-style-type: none"> <li>Could be hosted within a research institution</li> </ul>	<ul style="list-style-type: none"> <li>WHO</li> </ul>	<ul style="list-style-type: none"> <li>Could be incorporated into the Global Health R&amp;D Observatory</li> </ul>	<ul style="list-style-type: none"> <li>Decentralized (multiple companies can offer service and upload data)</li> </ul>	<ul style="list-style-type: none"> <li>Could be incorporated into the WHO ICTRP</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>
<b>Funding</b>	<ul style="list-style-type: none"> <li>Jointly funded by participating funders</li> </ul>	<ul style="list-style-type: none"> <li>WHO</li> </ul>	<ul style="list-style-type: none"> <li>WHO</li> </ul>	<ul style="list-style-type: none"> <li>Jointly funded by industry</li> </ul>	<ul style="list-style-type: none"> <li>WHO/International Health System</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>
<b>Governance</b>	<ul style="list-style-type: none"> <li>Could be governed by ESSENCE, given its multi-stakeholder, politically neutral status</li> </ul>	<ul style="list-style-type: none"> <li>WHO</li> </ul>	<ul style="list-style-type: none"> <li>WHO</li> </ul>	<ul style="list-style-type: none"> <li>Could be governed by industry association e.g. IFPMA</li> </ul>	<ul style="list-style-type: none"> <li>Could be governed by ESSENCE, given its multi-stakeholder, politically neutral status</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>

<sup>45</sup> More on GARDIAN here at <http://gardian.bigdata.cgiar.org/>

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## 7 APPENDIX

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### 7.1 KEY INFORMANT INTERVIEWS

*Table 7: Investment in research capacity strengthening by type and level of capacity*

Sn	Name	Institution/Designation
<i>Completed</i>		
1	Peter Kilmarx	Fogarty NIH
2	Hannah Akuffo	SIDA
3	Simon Kay	Wellcome Trust
4	Linda Kupfer	Fogarty NIH
5	Brad Wilken	Gates Foundation
6	Ole Olesen EDCTP	EDCTP
7	Nadia Khelef	Institute Pasteur, France
8	Garry Aslanyan	Coordinator, ESSENCE
9	Nicole Lurie	CEPI
10	Vasee Moorthy	WHO/GCM
11	Dr. Thabi Maitin	MRC South Africa
12	Dr. Rodrigo Correa-Oliveira	Fiocruz, Brazil
13	Dr. Luis Gabriel Cuervo	PAHO
14	Anne Kelso	GACD
15	John Reeder	TDR
16	Michael Cheetham	World Report
17	Tony Tse	US NLM ClinicalTrials.Gov
18	Yaso Kunaratnam	UKCDR
19	Margaret McCluskey	USAID/IAVI
20	Matthew Barnhart	USAID IAVI
21	Nick Day	Wellcome/SE Asia Clinical Research Centres
22	Thy Pham	Senior Program Officer Gates Foundation (GH & AAS)
23	Adama Ibrahim	Emerging Markets Quality Trials
24	Adam Taghreed	Global Observatory on Health R&D

25	Karam Ghassan	ICTRP2
<i>Not Yet Completed</i>		
1	Kabir Sheikh	APHSR
2	Anna Thorson	HRP
3	Andreas Lois	WHO Global Health Ethics
4	RESIN	University of Southampton
5	Nick Chapman	G-Finder
6	Gerald "Jerry" Keusch	University School of Medicine
7	Mukesh Chawla	World Bank
8	Anna Ruddock	Wellcome Trust
9	Dr. Glenda Gray	MRC South Africa
10	Prof. Balram Bhargava	ICMR (Indian Council of MR)
11	Val Snewin	DHSC, UK
12	Jennifer Stuart	DHSC, UK
13	Professor Trudie Lang	The Global Health Network
14	Shahid Jameel	ED, India Alliance
15	Roger Coker	Expert SE Asia
16	Sam Franzen	Expert LMIC Clinical Trials
17	Liz Bohm	AMS
18	Imelda Bates	LSTM
19	Dr Marta Tufet	ED, UKCDR
20	Dr Peter Dukes	Africa Research Excellence Fund

## 7.2 DEFINITION/CHARACTERIZATION OF RC & RCS

Table 8: Investment in research capacity strengthening by type and level of capacity

Whose Capacity?	What Capacity?		
	<i>Demand research</i>	<i>Produce knowledge</i>	<i>Use evidence</i>
Individual	<ul style="list-style-type: none"> <li>▪ Leadership for health research</li> </ul>	<ul style="list-style-type: none"> <li>▪ Disciplinary knowledge and expertise</li> <li>▪ Research techniques and methodologies</li> </ul>	<ul style="list-style-type: none"> <li>▪ Use of research in policy and practice</li> </ul>
Institutional	<ul style="list-style-type: none"> <li>▪ Organizational culture</li> <li>▪ Institutional leadership</li> <li>▪ Institutional independence</li> <li>▪ External collaboration</li> </ul>	<ul style="list-style-type: none"> <li>▪ Critical mass of research staff and support staff</li> <li>▪ Infrastructure (hard) <ul style="list-style-type: none"> <li>○ <i>Office space and equipment</i></li> <li>○ <i>Laboratory and laboratory equipment</i></li> </ul> </li> <li>▪ Infrastructure (soft) <ul style="list-style-type: none"> <li>○ <i>Data management</i></li> </ul> </li> <li>▪ Infrastructure (enabling) <ul style="list-style-type: none"> <li>○ <i>Power</i></li> <li>○ <i>Connectivity</i></li> <li>○ <i>Transportation</i></li> </ul> </li> <li>▪ Process and quality management standards <ul style="list-style-type: none"> <li>○ <i>Ethical review</i></li> <li>○ <i>Good Practice</i></li> </ul> </li> <li>▪ Funding &amp; financing for clinical research</li> </ul>	<ul style="list-style-type: none"> <li>▪ Community Engagement</li> </ul>
National	<ul style="list-style-type: none"> <li>▪ Culture</li> <li>▪ Political context/enabling legislation</li> <li>▪ Agenda setting and prioritization</li> </ul>	<ul style="list-style-type: none"> <li>▪ Domestic funding</li> <li>▪ Regulation/regulatory capabilities</li> <li>▪ Coordination (incl. emergency response contexts)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Co-ordination</li> </ul>
Macro (Intl., Regional, Supranational)	<ul style="list-style-type: none"> <li>▪ International relationships (donors, funders of research, south-south/north south collaboration)</li> <li>▪ Regional and international research networks</li> <li>▪ Governance, accountability and sustainability</li> </ul>		

### 7.3 SUMMARY OF IVTF RECOMMENDATIONS

<b>1</b>	By December 2018, in order to effectively respond to disease outbreaks, reduce preventable deaths, strengthen productivity and improve quality of life, countries should commit to strengthening capacity to conduct or participate in clinical research to address their public health needs
<b>2</b>	Recognizing the existing IDA18 commitment to strengthen preparedness in at least 25 countries, the World Bank Group should include, as a part of its IDA Mid-Term (December 2018) Review (MTR), an investment framework for national and regional clinical research capacities.
<b>3</b>	By end 2019, WHO should develop and disseminate examples of broadly applicable legislation and policies to support and enable efficient conduct of clinical research. This should include, at a minimum, model policies and laws that support the conduct of trials, enable timely ethics and regulatory review, address import/export of relevant commodities and bio-specimens, and address procurement and contracting systems. These policies should be a part of a broader governance architecture for clinical research.
<b>4</b>	By 2019, Research Forums/Institutions and/or Academies of Science in LMICs, drawing upon their experience and that of others, should synthesize best practices and develop guidance for consideration by countries on how to build a supportive research climate/culture
<b>5</b>	By end 2018, WHO should consolidate a robust set of indicators, to the extent possible building on indicators already used by countries, develop a tool for assessment of country-level capacities for clinical research, and propose a process to help countries rapidly conduct these assessments.
<b>6</b>	By end 2019, governments in IDA-eligible countries should commit short- and medium-term resources to address their clinical research capacity goals. These resources could potentially come from their IDA portfolios.
<b>7</b>	By end 2018, the World Bank Group should develop mechanisms to buy down IDA loans and convert them into grants for countries that have demonstrated development of research capacity based on agreed milestones.
<b>8</b>	The World Bank Group should encourage IDA countries to establish or leverage existing regional partnerships for developing clinical research capacity, using the IDA Regional Window funds combined with domestic commitments. The World Bank Group should highlight progress and showcase strategic development outcomes of such regional partnerships in the IDA18 MTR (December 2018), and develop a robust case for inclusion of prioritized regional clinical research partnerships as a thematic area under IDA19 (January 2020).
<b>9</b>	By end 2018, the World Bank Group should collaborate with development partners and other research funders to incentivize domestic resource mobilization in developing countries for investment in clinical research capacity, including by such means as matching grants and other incentivizing mechanisms.
<b>10</b>	By mid-2018, CEPI should commit resources to strengthening clinical research capacities in LMICs where clinical trials for vaccines against CEPI priority pathogens are likely to be conducted.
<b>11</b>	By end 2019, the private sector pharmaceutical/ biotech industry/clinical research organizations/ other health sector businesses operating in LMICs should announce their commitment to maximize their contribution to clinical research capacity in LMICs. This includes transfer of skills and expertise and/or allocating a percentage of their spending to

	support the development of clinical research capacity in LMICs that is aligned with country public health needs and national research agenda.
<b>12</b>	By end 2019, ESSENCE, in collaboration with the Global Coordination Mechanism and reinforced with additional LMIC representation, should articulate a mechanism that permits a thorough review of current and planned investments in research capacity strengthening. This should be done in consultation with major external funders of clinical research (including those involved in capacity strengthening of network, laboratory, ethics, and regulatory capability). This collaborative mechanism should ensure synergy at country and regional levels, and streamline the administrative burden experienced by institutions dealing with multiple research funders.
<b>13</b>	By the end of 2018, the World Bank Group, working through the PEF and CEPI Trust Fund mechanisms, should establish a rapid financing vehicle to support the priority outbreak-related research agenda emerging from the WHO R&D Blueprint, and to strengthen in-country capacity, including the conduct of clinical research as part of outbreak response
<b>14</b>	By June 2019, based on experience accumulated by countries, WHO and the World Bank Group should develop a resource tracking tool enabling governments to monitor and track, at a national level, all funding that supports clinical research capacity-building activities within the country and accounts for the multiplicity of funders involved.
<b>15</b>	Reviewing progress on the implementation of these recommendations should inform the agenda of the Global Preparedness Monitoring Board.

## 7.4 HIGH LEVEL PROFILES OF SELECTED RELEVANT MECHANISMS

### **High level profiles of selected mechanisms relevant to the coordination of investments in clinical research capacity strengthening/building**

Following an extensive review of existing literature on enhancing collaboration, synergy and impact of investments in clinical research capacity strengthening, the under-listed mechanisms were identified.

1. The Special Programme for Research and Training in Tropical Diseases – TDR
2. ESSENCE
3. World Report
4. The Global Observatory on Health R&D
5. WHO Clinical Trials Registry
6. Clinicaltrials.gov – The US National Library of Medicine
7. ISRCTN Registry
8. EU Clinical Trial Register
9. PACTR
10. UKCDR
11. PAHO
12. West African Health Organization
13. EDCTP
14. AMR Cross Council Initiative
15. Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)
16. Global AMR R&D Hub
17. West African Health Organization
18. Asia Pacific Observatory on Health Systems and Policies (the APO)
19. Institute Pasteur
20. Coalition for Epidemic Preparedness Innovations
21. Alliance for Health Policy and Systems Research (AHPSR)
22. Council on Health Research for Development (COHRED)
23. The Centre for Integration of Data and Health Knowledge
24. Intl. Federation of PharmaManufacturers & Associations
25. Global Coordination Mechanism on R&D Blueprint (GCM)
26. Program of R&D in Human Reproduction (HPR)

### **1. The Special Programme for Research and Training in Tropical Diseases – TDR**

Established in 1975, the Special Programme for Research and Training in Tropical Diseases(TDR) is hosted at the World Health Organization (WHO),and is sponsored by the United Nations Children’s Fund (UNICEF), the United Nations Development Program (UNDP), the World Bank and WHO. TDR is a global program of scientific collaboration that helps facilitate, support, and influence efforts to combat diseases of poverty.<sup>46</sup> Since its earliest days, TDR has been committed to the two interdependent objectives of supporting research to improve the control of infectious diseases, and strengthening the capacity of disease-affected countries to perform valuable health research themselves.<sup>47</sup> The mission of the TDR is “To support effective and innovative global health research, through strengthening the research capacity

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<sup>46</sup> <https://www.who.int/tdr/about/en/>

<sup>47</sup> TDR Strategy 2018 – 2023: Building the science of solutions

of disease-affected countries, and promoting the translation of evidence into interventions that reduce the burden of infectious diseases and build resilience in the most vulnerable populations.”For more than forty years, TDR has been a leader in research to address infectious diseases of poverty, and in building the capacity of institutions, individuals and communities in disease-affected countries to generate the evidence and put in place the innovations needed to improve their health. TDR’s twin mission of supporting research and increasing research capacity has created new tools and strategies that led to health improvements. For example, promoting basic research and product development on infectious diseases of poverty, at a time when little of this work was supported, paid dividends in new interventions that supported disease elimination campaigns. The TDR model which pioneered today’s product development and public/private partnerships resulted in a dozen new drugs for infectious diseases.

## **2. The WHO Global Observatory on Health R&D**

The Global Observatory on Health R&D ‘the Observatory’ is a global-level initiative that aims to help identify health R&D priorities based on public health needs, by:

- consolidating, monitoring and analysing relevant information on the health R&D needs of developing countries;
- building on existing data collection mechanisms; and
- supporting coordinated actions on health R&D.<sup>48</sup>

Investments in health R&D are still insufficiently aligned with global public health demands and needs. As little as 1% of all funding for health R&D is allocated to diseases such as malaria and tuberculosis (diseases that are predominantly incident in developing countries), despite these diseases accounting for more than 12.5% of the global burden of disease. The recent outbreak of Ebola virus disease dramatically exposed the lack of investment in products and approaches to prevent and minimize the impact of pathogens with epidemic potential. Recently, the gaps in R&D investments and the pipeline for antimicrobial medicines have also become a cause of global concern in the context of rapidly increasing antimicrobial resistance. Governments, policy-makers, funders and researchers therefore need an accurate picture of the current situation so as to spot R&D gaps and ensure that funds and resources are used in the best possible way.

In May 2013, the Sixty-sixth World Health Assembly specifically mandated the establishment of the Observatory in resolution WHA66.22, with the overall goal “to consolidate, monitor and analyze relevant information on health research and development activities, ... with a view to contributing to the identification and the definition of gaps and opportunities for health research and development priorities, and supporting coordinated actions on health research and development.”

The Sixty-ninth World Health Assembly (May 2016) re-emphasized the Observatory’s central role and the importance of expediting its development. In resolution WHA69.23 it also requested the establishment of an expert committee on health R&D to set priorities for new investments based on information primarily provided by the Observatory.

In addition, WHO Member States requested that the WHO Director-General ensure the R&D needs relating to the following two specific areas of health concern (where current markets and business models are failing) are tracked through the Observatory:

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<sup>48</sup> [https://www.who.int/research-observatory/why\\_what\\_how/en/](https://www.who.int/research-observatory/why_what_how/en/)



- antimicrobial resistance and the need to develop new medical products to protect populations from the risks of failing treatments against infectious pathogens (see resolution WHA67.25 of the Sixty-seventh World Health Assembly in May 2014);
- a comprehensive R&D Blueprint preparedness plan that allows the rapid activation of R&D activities during future epidemics, such as the epidemic that occurred due to Ebola virus disease. (see EB138/28 of the 138th session of the WHO Executive Board).

The primary scope of the Observatory as outlined by Member States in World Health Assembly resolution WHA69.23 is:

- type II and type III diseases (i.e. diseases incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries, and diseases that are overwhelmingly or exclusively incident in developing countries respectively);
- the specific R&D needs of developing countries in relation to type I diseases (i.e. diseases incident in both rich and poor countries, with large numbers of vulnerable populations in each);
- potential areas where market failures exist;
- antimicrobial resistance and on emerging infectious diseases likely to cause major epidemics.

The Observatory will be of use to governments, policy-makers, funders, researchers and civil society, to: review and query information on current trends, for example, in investment in health R&D, products in the pipeline and clinical trials;

- look at comparisons of R&D activities between countries, diseases and in relation to relevant information such as burden of disease or macroeconomic indicators;
- review global indicators on health R&D in the context of the Sustainable Development Goals (SDGs); or more generally
- consult comprehensive disease-specific analyses on identified needs and priorities (where set); find relevant key publications, databases and resources; consult the classifications and standards in use by the Observatory as a step towards galvanizing wider discussion and consensus to harmonize approaches to collect and share R&D data.

Since its inception, the Global Observatory on Health R&D has received funding support from various sources to support its establishment and expansion, including:

- European Commission
- Government of France
- Government of Germany
- Government of Switzerland
- Government of the United States of America

### 3. The World Report

The World RePORT is hosted by the United States of America's National Institutes of Health and managed through a steering committee of the agencies providing data.<sup>49</sup> To date, the World RePORT includes data reported by 12 major funders of health research. Not all of these funders report on a yearly basis. For example, in 2015 only 9 of the 12 funders reported data (for grants in 2015).

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<sup>49</sup> <https://worldreport.nih.gov/app/#!//>

Collectively, 8 of the 12 funders that have reported since 2012 make up approximately 78% of the annual health research expenditures of 55 major public and philanthropic funders of health research according to Viergever & Hendriks 2015. The 12 major funders of health research are:

1. Bill and Melinda Gates Foundation <https://www.gatesfoundation.org/>
2. Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/193.html>
3. European Commission [https://ec.europa.eu/commission/index\\_en](https://ec.europa.eu/commission/index_en)
4. European and Developing Countries Clinical Trials Partnership <http://www.edctp.org/>
5. Institut national de la santé et de la recherche médicale (French National Institute of Health and Medical Research) <https://www.inserm.fr/en>
6. Max – Planck – Gesellschaft <https://www.mpg.de/11761628/profile-visions>
7. Medical Research Council UK (MRC) <https://mrc.ukri.org/>
8. National Institutes of Health (NIH) <https://www.nih.gov/>
9. Institut Pasteur <https://www.pasteur.fr/en>
10. SIDA – Swedish International Development Cooperation Agency <https://www.sida.se/English/>
11. Swedish Research Council <https://www.vr.se/english.html>
12. Wellcome <https://wellcome.ac.uk/>

#### 4. ESSENCE

ESSENCE on Health Research is an initiative that allows donors and funders to identify synergies, bring about coherence and increase the value of resources and actions for health research. Its focus is on low- and middle-income countries.<sup>50</sup> Over the past several decades the value and impact of funding for health research has been given increasing importance. The result has been a sharp rise in uncoordinated and fragmented funding of an increased number of initiatives and projects. Recognizing that such fragmentation and lack of coordination wastes time and effort, the ESSENCE initiative aims to promote better strategic cooperation between partners, particularly among bilateral development agencies and funding organizations.

The goal of ESSENCE is to increase the impact of support provided for research capacity strengthening for health in low- and middle-income countries.

ESSENCE executes its mandate by undertaking the following key activities:

- Policy Dialogue – Facilitating enhanced policy dialogue between the funders of research for health to align voices for strong advocacy.
- Harmonization – Piloting a number of innovative approaches to achieve harmonization and optimization of resources, including the development of best practice guidance documents.
- Country Pilots – Promoting the development and implementation of national strategies for research and related country-based pilot models of collaboration between programmes.
- Evaluation – Improving methodologies, monitoring and evaluation indicators to track input, process, outcomes and the impact of investment in capacity development.

ESSENCE members include some of the top funders of health research around the world – primarily health research funding agencies – and also international health institutions, government research agencies, development agencies, philanthropists and multilateral initiatives. ESSENCE on Health Research members are advised by a Steering Committee, which presently has seven members, representing Wellcome Trust, United Kingdom; Swedish International Development Cooperation Agency (SIDA), Sweden; Fogarty

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<sup>50</sup> <http://www.who.int/tdr/partnerships/initiatives/essence>

International Center – National Institutes of Health, USA; Institut Pasteur, France; European and Developing Countries Clinical Trials Partnership (EDCTP), Netherlands, United States Agency for International Development (USAID); South African Medical Research Council (SAMRC), South Africa; International Development Research Centre (IDRC), Canada; the Special Programme of Research, Development and Research Training in Human Reproduction, WHO, Geneva; and the Special Programme for Research and Training in Tropical Diseases (TDR) as the Secretariat of the initiative.

## 5. The WHO International Clinical Trials Registry Platform (ICTRP)

The establishment of the ICTRP followed the Ministerial Summit on Health Research that took place in Mexico City in November 2004 where participants called on the WHO to facilitate the establishment of: *"a network of international clinical trials registers to ensure a single point of access and the unambiguous identification of trials"*. This was further expanded on during the 58th World Health Assembly in Resolution WHA58.22 that called on the global scientific community, international partners, the private sector, civil society, and other relevant stakeholders to: *"establish a voluntary platform to link clinical trials registers in order to ensure a single point of access and the unambiguous identification of trials with a view to enhancing access to information by patients, families, patient groups and others"*

The main aim of the WHO ICTRP is to facilitate the prospective registration of the WHO Trial Registration Data Set on all clinical trials, and the public accessibility of that information.<sup>51</sup> The WHO Registry Network provides prospective trial registries with a forum to exchange information and work together to establish best practice for clinical trial registration.

The WHO Registry Network is composed of:

- Primary Registries
- Partner Registries
- Data Providers
- Registries working with the ICTRP towards becoming Primary Registries

### Which Clinical Trial Registries can be part of The WHO Registry Network?

Any registry that enters clinical trials into its database prospectively (that is, before the first participant is recruited), and meets the WHO Registry Criteria or that is working with ICTRP towards becoming a Primary Registry can be part of the WHO Registry Network.

**Primary Registries in the WHO Registry Network** - Primary Registries in the WHO Registry Network meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries meet the requirements of the International Committee of Medical Journal Editors (ICMJE).

The registries that currently meet these criteria are:

- 1) Australian New Zealand Clinical Trials Registry (ANZCTR)
- 2) Brazilian Clinical Trials Registry (ReBec)
- 3) Chinese Clinical Trial Registry (ChiCTR)
- 4) Clinical Research Information Service (CRiS), Republic of Korea
- 5) Clinical Trials Registry - India (CTRI)
- 6) Cuban Public Registry of Clinical Trials (RPCEC)
- 7) EU Clinical Trials Register (EU-CTR)
- 8) German Clinical Trials Register (DRKS)
- 9) Iranian Registry of Clinical Trials (IRCT)

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<sup>51</sup> <https://www.who.int/ictip/about/en/>

- 10) ISRCTN
- 11) Japan Primary Registries Network (JPRN)
- 12) Thai Clinical Trials Registry (TCTR)
- 13) The Netherlands National Trial Register (NTR)
- 14) Pan African Clinical Trial Registry (PACTR)
- 15) Peruvian Clinical Trial Registry (REPEC)
- 16) Sri Lanka Clinical Trials Registry (SLCTR)

**Partner Registries** –All Partner Registries must also be affiliated with either a Primary Registry in the WHO Registry Network or an ICMJE approved registry. The ICTRP Secretariat is unable to receive data directly from Partner Registries. It is the responsibility of Primary Registries in the WHO Registry Network to ensure that their Partner Registries meet WHO Registry Criteria.

## **6. Clinicaltrials.gov – The US National Library of Medicine**

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine. It was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA required the U.S. Department of Health and Human Services (HHS), through NIH, to establish a registry of clinical trials information for both federally and privately funded trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for serious or life-threatening diseases or conditions. NIH and the Food and Drug Administration (FDA) worked together to develop the site, which was made available to the public in February 2000.<sup>52</sup> ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The Web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information on the site is updated throughout the study. In some cases, results of the study are submitted after the study ends. This Web site and database of clinical studies is commonly referred to as a "registry and results database." ClinicalTrials.gov contains information about medical studies in human volunteers. Most of the records on ClinicalTrials.gov describe clinical trials (also called interventional studies). A clinical trial is a research study in which human volunteers are assigned to interventions (for example, a medical product, behavior, or procedure) based on a protocol (or plan) and are then evaluated for effects on biomedical or health outcomes. ClinicalTrials.gov also contains records describing observational studies and programs providing access to investigational drugs outside of clinical trials (expanded access). Studies listed in the database are conducted in all 50 States and in 207 countries. ClinicalTrials.gov does not contain information about all the clinical studies conducted in the United States because not all studies are required by law to be registered (for example, observational studies and trials that do not study a drug, biologic, or device). See FDAAA 801 and the Final Rule for more information. However, the rate of study registration has increased over time as more policies and laws requiring registration have been enacted and as more sponsors and investigators have voluntarily registered their studies.

## **7. ISRCTN Registry**

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<sup>52</sup> <https://clinicaltrials.gov/ct2/about-site/background>

The ISRCTN registry is a primary clinical trial registry recognised by WHO and ICMJE that accepts all clinical research studies (whether proposed, ongoing or completed), providing content validation and curation and the unique identification number necessary for publication. All study records in the database are freely accessible and searchable. ISRCTN supports transparency in clinical research, helps reduce selective reporting of results and ensures an unbiased and complete evidence base.<sup>53</sup> ISRCTN registry is supported by the Department of Health – UK, Medical Research Council – UK, Wellcome Trust and Canadian Institutes of Health Research.

## **8. EU Clinical Trial Register**

The EU Clinical Trials Register contains information on interventional clinical trials on medicines conducted in the European Union (EU), or the European Economic Area (EEA) which started after 1 May 2004. Clinical trials conducted outside the EU/EEA are included if:

- they form part of a Paediatric Investigation Plan (PIP), or:
- they are sponsored by a marketing authorisationholder, and involve the use of a medicine in the paediatric population as part of an EU marketing authorisation.

The Register also provides information about older paediatric trials covered by an EU marketing authorisation. The Register enables users to search for information in the EudraCT database External link. This is the database used by national medicines regulators for data related to clinical trial protocols. The data on the results of these trials are entered into the database by the sponsors themselves and are published in this Register once the sponsors have validated the data.

The EU clinical trials register has been a primary registry in the World Health Organization (WHO's) Registry Network since September 2011 and is a WHO Registry Network data provider. It is also available on the WHO International Clinical Trials Registry Platform External link.

## **9. PACTR**

The PACTR is currently funded by the EDCTP and managed by the South African Cochrane Centre (SACC), an intra-mural research unit of the South African Medical Research Council (MRC). The SACC is funded by the MRC and the PACTR is funded for the following year on a no-cost extension by the EDCTP to complete its development phase.<sup>54</sup> The registry accepts registration of clinical trials from all countries in Africa. It is a primary registry in the WHO ICTRP.

## **10. UK Collaborative on Development Research (UKCDR)**

The UK Collaborative on Development Research (UKCDR) is a group of government departments and research funders working in international development. For over a decade, the UKCDR has brought UK research funders together to discuss priorities and coordinate efforts to garner maximum impact. Governed by the Strategic Coherence of ODA-funded Research (SCOR) Board, the mission of the UKCDR is to “amplify the value and impact of research for global development by promoting coherence, collaboration and joint action among UK research funders”.<sup>55</sup> The UKCDR anchors its strategy on the following overlapping aims:

- A collective voice to shape policy
- Mapping, analysis and foresight
- Convening for collaboration and joint action

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<sup>53</sup> <http://www.isrctn.com/>

<sup>54</sup> <https://www.who.int/ictip/network/pactr/en/>

<sup>55</sup> <https://www.ukcdr.org.uk/about-us/our-mission-and-strategy/>

- Sharing information, learning and best practice

The core contributing members of the UKCDR are:

- Department for International Development (DFID)
- Department for Business, Energy and Industrial Strategy (BEIS)
- Department for Health and Social Care (DHSC)
- UK Research and Innovation (UKRI)
- Wellcome Trust

Other members of the UKCDR include the Foreign and Commonwealth Office (FCO), the Department for Environment, Food and Rural Affairs (DEFRA), the Government Office for Science and the devolved government administrations in the UK. The wider stakeholders include the UK and international research community, research funding delivery partners, and the NGO, philanthropic and private sectors.

## **11. Pan American Health Organization PAHO**

Established in December 1902, PAHO is the specialized international health agency for the Americas. With 27 offices and three specialized centers in the region, PAHO promotes evidence-based decision-making to improve and promote health as a driver of sustainable development. It works with countries throughout the region to improve and protect people's health. PAHO engages in technical cooperation with its member countries to fight communicable and non-communicable diseases and their causes, to strengthen health systems, and to respond to emergencies and disasters. PAHO is committed to ensuring that all people have access to the health care they need, when they need it, with quality and without fear of falling into poverty. Through its work, PAHO promotes and supports the right of everyone to good health. To advance these goals, PAHO promotes technical cooperation between countries and works in partnership with ministries of health and other government agencies, civil society organizations, other international agencies, universities, social security agencies, community groups, and other partners. PAHO promotes the inclusion of health in all public policies and the engagement of all sectors in efforts to ensure that people live longer, healthier lives, with good health as their most valuable resource. Under the leadership of its 52 member countries and territories, PAHO sets regional health priorities and mobilizes action to address health problems that respect no borders and that, in many cases, jeopardize the sustainability of health systems.<sup>56</sup>

PAHO wears two institutional hats: it is the specialized health agency of the Inter-American System and also serves as Regional Office for the Americas of the World Health Organization (WHO), the specialized health agency of the United Nations.

## **12. European & Developing Countries Clinical Trials Partnership (EDCTP)**

The European & Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003 as a European response to the global health crisis caused by the three main poverty-related infectious diseases, HIV/AIDS, tuberculosis (TB) and malaria. Part of the European Commission's Framework Programmes, EDCTP brings together European Union (EU) Member States plus Norway, sub-Saharan African countries, pharmaceutical companies, small and medium enterprises (SMEs), product development partnerships (PDPs) and international foundations to advance the development of vaccines, drugs, diagnostics and other interventions targeting poverty-related infectious diseases affecting sub-Saharan Africa<sup>57</sup>.

<sup>56</sup> [https://www.paho.org/hq/index.php?option=com\\_content&view=article&id=91:about-paho&Itemid=220&lang=en](https://www.paho.org/hq/index.php?option=com_content&view=article&id=91:about-paho&Itemid=220&lang=en)

<sup>57</sup> <http://www.edctp.org/web/app/uploads/2018/12/The-added-value-of-EDCTP-to-Africa.pdf>

EDCTP's mission is to accelerate the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies, with emphasis on phase II and III clinical trials. EDCTP's approach integrates conduct of research with development of African clinical research capacity and networking<sup>58</sup>. The added value of EDCTP in Africa is evident in multiple ways and at different levels –

- Contributing to the achievement of the African Union
- Creating and retaining a new generation of African scientists
- Strengthening and harmonising enablers of high-quality and ethical clinical research
- Contributing to the provision of safe medical interventions
- Promoting demand-driven research
- Bridging the gap between science and policy for health
- Promoting cross-border engagements across Africa
- Ensuring transparency in clinical trials to inform health research
- Boosting preparedness for infectious disease outbreaks in Africa
- Supporting integrated capacity building for health research in Africa

### **13. AMR Funders Forum**

To coordinate and prioritise the UK's research response to the UK AMR 2013-2018 strategy, the Medical Research Council (MRC) established the [UK AMR Funders Forum \(AMRFF\)](#)<sup>59</sup>, which brings together 21 research funders, including the UK Research and Innovation councils, government departments, devolved administrations and charities. AMRFF provides a forum for the sharing of information on activities relating to AMR, and a framework for a more coordinated approach to tackling AMR research to maximise impact on national and international policies and activities. The Forum has identified four key research themes to target investments.

### **14. AMR Cross Council Initiative**

This inter-disciplinary [AMR cross-council initiative](#) is focused on the AMRFF four themes to supporting research encompassing academia, biopharma, diagnostic companies, veterinary and the health service. The current focus of this initiative is on resistant bacteria of humans and animals. Governance is overseen by a top-level Steering Group to provide scientific guidance and ensure delivery and an Executive Group of funding partners. Membership of the Steering Group includes experts that cross the remit of the research councils. Each theme has its own Expert Scientific Panel to assess the research programmes.

### **15. Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)**

[JPIAMR](#) is an international collaborative platform that coordinates national research funding, multidimensional AMR research and funding on a global scale and supports collaborative action for filling knowledge gaps on AMR with a One Health perspective. It brings together 27-member nations. A shared

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<sup>58</sup> [http://www.edctp.org/web/app/uploads/2018/09/Tackling-infectious-disease-in-sub-Saharan-Africa\\_EDCTP-funded-clinical-studies-for-medical-interventions-2003-2018-4.pdf](http://www.edctp.org/web/app/uploads/2018/09/Tackling-infectious-disease-in-sub-Saharan-Africa_EDCTP-funded-clinical-studies-for-medical-interventions-2003-2018-4.pdf)

<sup>59</sup> AHRC, BBSRC, Chief Scientist Office, Scotland (CSO), BEIS, DFID, Defence Science and Technology Laboratory (Dstl), DEFRA, DHSC, ESRC, EPSRC, The Food Standard Agency (FSA), Health and Care Research Wales, HSC R&D Division, Public Health Agency, Northern Ireland, Innovate UK, MRC, NERC, National Institute of Health Research (NIHR), Public Health England (PHE), Science and Technology Facilities Research Council (STFC), Veterinary Medicines Directorate (VMD), Wellcome Trust.

Strategic Research Agenda outlines the key areas to address and provides guidance for countries to align their AMR research agendas nationally and internationally. Since its inception, JPIAMR has funded more than 50 research projects and networks with joint funds exceeding €65m to date.

## **16. Global AMR R&D Hub**

A new body announced at G20 2017 to coordinate the discovery and development of urgently needed antimicrobial drugs. The Global Antimicrobial Resistance Research and Development Hub – Global AMR R&D Hub for short – aims to further improve the coordination of international efforts and initiatives to tackle AMR while further increasing investments into R&D for AMR. Members are Ministries of Health and membership is open to both G20 and non-G20 states and other donors. The German Federal Government has taken the lead in driving the establishment of the Global AMR R&D Hub. Initially, the secretariat of the Global AMR R&D Hub will be based in Berlin, at the German Center for Infection Research (DZIF). The Federal Ministry of Education and Research (BMBF) will provide up to 500 million euros over the next ten years towards research to combat antimicrobial resistance. The hub will work with existing partnerships, such as CARB-X.

## **17. West African Health Organization**

The West African Health Organization (WAHO) is the regional Agency charged with the responsibility of safeguarding the health of the peoples in the sub-region through the initiation and harmonization of the policies of Member States, pooling of resources, and cooperation with one another and with others for a collective and strategic combat against the health problems of the sub-region.

Established in 1987 when the Heads of State and Government from all fifteen countries in the Economic Community of West African States (ECOWAS) adopted the Protocol creating the organization and each government subsequently ratified it, WAHO has transcended linguistic borders and hurdles in the sub-region to serve all fifteen ECOWAS Member States. The Protocol, grants WAHO status as a Specialized Agency of ECOWAS and describes the organization's mission as 'the attainment of the highest possible standard and protection.'

**Vision and strategies:**WAHO is a proactive instrument of regional health integration that enables high-impact and cost-effective interventions and programs by:

- Maintaining sustainable partnerships
- Strengthening capacity building
- Collecting, interpreting and disseminating information
- Promoting cooperation and ensuring coordination and advocacy
- Exploiting information communication technologies

WAHO has through its strategic programs, undertaken measures to combat Malaria, malnutrition, HIV/AIDS, maternal and infant mortality; prevention of blindness actions for easy access to medicines and vaccines, epidemiological surveillance as well as training and health information management in the sub-region. Also, via its second strategic plan, WAHO is implementing strategic orientations such as; support for quality improvement of the health systems of the sub-region, support for health services improvement in the sub-region, support for development of sustainable financing of health and Institutional development of WAHO. This is implemented through various programs.

## **18. Asia Pacific Observatory on Health Systems and Policies (the APO)**

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APO is a collaborative partnership of interested governments, international agencies, foundations, and researchers that promotes evidence-informed health system policy regionally and in all countries in the Asia Pacific region.

The APO collaboratively identifies priority health system issues across the Asia Pacific region, develops and synthesizes relevant research to support and inform countries' evidence-based policy development; and builds country and regional health systems research and evidence-informed policy capacity.

The APO's main functions are to:

- Establish a body of knowledge and evidence on health systems in the Asia Pacific region, comparable across countries, through collection and analysis of information and research evidence on health care policies and reforms
- Engage in in-country dialogue with key stakeholders, including government, development partners, civil society and academia, to facilitate a shared assessment of each health system's strengths and weaknesses that builds consensus on needed policy directions and helps develop evidence informed health policies within countries
- Develop and strengthen national and regional capacity in research, analysis and knowledge translation

The members of APO include: Asian Development Bank, Department of Foreign Affairs and Trade, Australia (DFAT), Fiji, Hong Kong SAR, Republic of Korea, Republic of the Philippines, Singapore, Sri Lanka, Thailand, World Bank, World Health Organization – Western Pacific Region and South-East Asia Region Offices.

## **19. Institute Pasteur**

The Institut Pasteur is a private, non-profit foundation that has been contributing to the history of science, medicine and public health for 130 years. Its mission is to help prevent and treat diseases, mainly those of infectious origin, through research, teaching, and public health initiatives. With an effective management policy and successful response strategy, the Management, Board of Directors and General Meeting board provide the impetus for the Institut Pasteur's research.<sup>60</sup> Located in 25 countries on five continents, the Institut Pasteur International Network (RIIP) associates 32 institutions, which are united by shared values and missions for the benefit of populations. It is a unique model for health cooperation and, in addition to its structures, brings together a human and scientific community that focuses on both local and international health priorities. Present in numerous endemic areas, the RIIP has, time and time again, demonstrated its major role as a sentinel for emerging infectious diseases.

## **20. Coalition for Epidemic Preparedness Innovations (CEPI)**

CEPI is an innovative global partnership between public, private, philanthropic, and civil society organisations launched in Davos in 2017 to develop vaccines to stop future epidemics. CEPI's mission is to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks.<sup>61</sup>

Many organisations operate within the end-to-end space of vaccine funding and R&D implementation. However, a number of critical gaps have been identified, which CEPI was designed to fill.

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<sup>60</sup> <https://www.pasteur.fr/en/institut-pasteur>

<sup>61</sup> <https://cepi.net/>

- First, CEPI will advance vaccines against known threats through proof-of-concept and safety testing in humans and will establish investigational vaccine stockpiles before epidemics begin—“just in case”.
- Second, we will fund new and innovative platform technologies with the potential to accelerate the development and manufacture of vaccines against previously unknown pathogens (eg: within 16 weeks from identification of antigen to product release for clinical trials)—“just in time”.
- Third, CEPI will support and coordinate activities to improve our collective response to epidemics, strengthen capacity in countries at risk, and advance the regulatory science that governs product development.

## 21. Alliance for Health Policy and Systems Research (AHPSR)

For two decades, the Alliance for Health Policy and Systems Research (the Alliance) has continued to work to improve the health of those in low- and middle-income countries by supporting the generation and use of evidence that strengthens health systems.<sup>62</sup> As an international partnership hosted by the World Health Organization, we Alliance works together with organizations around the world to:

- Provide a unique forum for the health policy and systems research community;
- Support institutional capacity for the conduct and uptake of health policy and systems research;
- Stimulate the generation of knowledge and innovations to nurture learning and resilience in health systems; and
- Increase the demand for and use of knowledge for strengthening health systems.

## 22. Council on Health Research for Development (COHRED)

COHRED, the Council on Health Research for Development, is a global, non-profit organization whose goal is to maximize the potential of research and innovation to deliver sustainable solutions to the health and development problems of people living in low and middle-income countries.<sup>63</sup> COHRED’s vision is that all low and low-middle income countries will have smarter and better resourced national research and innovation system for health in place by 2025 – so they can conduct, partner, commission or use research to address their own health priorities – take the lead in their own health, equity, socio-economic development and become key contributors to improving global health.

COHRED offers solutions in three ways:

- a. **Technical Support** – Expert analysis and support in research and innovation system analysis, priority setting, performance enhancement. COHRED also provides guidance to institutions and governments on how to negotiate better research contracts.
- b. **Practical Tools** – RHInnO Ethics is a unique, cloud-based research ethics management system – that accelerates and increases the quality of ethics review of health research, potentially shaving 12 months or more of getting products to users.
- c. **Global Action** – Through its Global Forum on Research and Innovation for Health and the Colloquium Series, COHRED provides a unique global platform to generate ideas, insights, inspiration and intelligence for its constituencies.

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<sup>62</sup> <https://www.who.int/alliance-hpsr/about/en/>

<sup>63</sup> <http://www.cohred.org/our-mission/>

### **23. Intl. Federation of PharmaManufacturers & Associations**

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.<sup>64</sup>

### **24. Program of R&D in Human Reproduction (HRP)**

HRP is the main instrument within the United Nations system for research in human reproduction, bringing together policy-makers, scientists, health care providers, clinicians, consumers and community representatives to identify and address priorities for research to improve sexual and reproductive health.<sup>65</sup>

HRP supports and coordinates research on a global scale, synthesizes research through systematic reviews of literature, builds research capacity in low-income countries and develops dissemination tools to make efficient use of ever-increasing research information. WHO is one of five cosponsors of HRP, along with UNDP, UNFPA, UNICEF, and the World Bank. In addition, the International Planned Parenthood Federation (IPPF) and UNAIDS are both members of HRP's governing body.

### **25. The Centre for Integration of Data and Health Knowledge (Cidacs)**

Cidacs is part of the Gonçalo Moniz Institute of the Oswaldo Cruz Foundation, and therefore has the same legal status. Cidacs is a complex of services, physical and human resources in integration with interdisciplinary scientific projects developed by multidisciplinary teams in the areas of epidemiology, statistics, bioinformatics, and computing, among other specialties. Its mission is to carry out studies and research, develop new investigative methodologies and promote professional and scientific training, based on interdisciplinary projects, based on the integration of large data bases ("big data"). With the help of available knowledge and high-performance computing resources inserted in a safe environment, CIDACS with its action will contribute to the production of innovative knowledge in order to broaden the understanding of the population's health problems, as well as to support decision-making in public policies for the benefit of society.<sup>66</sup>

Cidacs was created by decree 32-2016, linked to the board of directors of Fiocruz Bahia, with the following objectives:

- a. Conduct studies and research, develop new investigative methodologies and promote professional and scientific training, based on interdisciplinary projects and involving the integration of large databases ("big data");
- b. Promote the integration of knowledge at different levels (population, individual and sub-individual), with the purpose of broadening the scope of Health Sciences;
- c. With the help of available knowledge and high-performance computing resources in a secure environment, contribute to the production of innovative knowledge in order to broaden the understanding of the population's health problems, as well as to support decision-making in public policies , for the benefit of society;

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<sup>64</sup> <https://www.ifpma.org/>

<sup>65</sup> <https://www.who.int/life-course/partners/human-reproduction/en/>

<sup>66</sup> <https://cidacs.bahia.fiocruz.br/en/about/history/>

- d. To maintain a network of scientific interdisciplinary cooperation, with national and international partners, favoring and stimulating scientific and technological production in relevant and innovative aspects for the health of the population and for the SUS.

## **26. Global Coordination Mechanism on R&D Blueprint (GCM)**

On 28 March 2017, terms of reference for the Global Coordination Mechanism (GCM) for R&D preparedness were discussed at its first formal meeting in London. The primary role of the GCM is to build a consensual voluntary framework for key stakeholders to address global R&D challenges during epidemics. The second objective is to provide a high-level discussion platform and enable sharing of strategic directions, nurturing collaborations and, addressing crucial gaps, without duplication of efforts.<sup>67</sup>

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<sup>67</sup> [https://www.who.int/blueprint/what/improving-coordination/global\\_coordination\\_mechanism/en/](https://www.who.int/blueprint/what/improving-coordination/global_coordination_mechanism/en/)

## 7.5 APPROACH TO DEVELOPING THE BACKGROUND PAPER

	Week 1	Week 2-10		Week 11-12
Phase	1. Develop inventory of data sources	2. Conduct data analysis, literature review, stakeholder interviews, 3. Iteratively synthesise key findings and draft interim papers		4. Refine/prepare final paper
Objectives	<ul style="list-style-type: none"> <li>Develop prioritized list of literature to be reviewed and key experts/stakeholders to consult</li> </ul>	<ul style="list-style-type: none"> <li>Provide informative context and evidence-based information on clinical research capacity, and clinical research capacity strengthening in LMICs</li> </ul>	<ul style="list-style-type: none"> <li>Synthesize available information and expert input to guide the consideration of potential models for a mechanism for the review of investments in clinical research capacity building in LMICs</li> </ul>	<ul style="list-style-type: none"> <li>Perform final synthesis of key findings and incorporate feedback</li> <li>Prepare final paper</li> </ul>
Main activities	<ul style="list-style-type: none"> <li>Desk research</li> <li>Stakeholder outreach to solicit input</li> <li>Prioritization of data sources</li> <li>Data gathering</li> </ul>	<ul style="list-style-type: none"> <li>Examine current characterization of clinical research capacity/clinical research capacity building</li> <li>Examine dimensions, &amp; identify key components and metrics</li> <li>Identify existing resources for assessing capacity/cap. building</li> <li>Identify opportunities for synergy/standardization</li> <li>Summarize current perspectives on capacity/capacity building in LMICs</li> </ul>	<ul style="list-style-type: none"> <li>Examine current systematic activities or mechanisms in place to coordinate or collaborate investments in clinical research capacity building</li> <li>Identify desired characteristics of a review mechanism</li> <li>Identify possible models from other fields that could be adopted</li> <li>Suggest strategic options for a review mechanism and outline their respective pros and cons</li> </ul>	<ul style="list-style-type: none"> <li>Incorporate feedback and input from experts into previous drafts</li> <li>Drafting of final background paper</li> </ul>
Deliverables	<p>★ Nov 12<sup>th</sup>: Start</p> <p>★ Nov 19<sup>th</sup>: research plan/ inventory of data sources</p>	<p>★ Dec 3<sup>rd</sup>: Outline &amp; Interim Paper #1</p>	<p>★ Jan 7<sup>th</sup> Interim Paper #2</p>	<p>★ Feb 4<sup>th</sup>: Submit final paper</p>

## 7.6 METRICS FOR ASSESSING NATIONAL BIOMEDICAL RESEARCH CAPACITY

### Metrics for national biomedical research capacity

Developed for the World Bank International Vaccines Task Force

January 29, 2018

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#### Background:

The World Bank has convened an *International Task Force on Strengthening Country Capacity for Vaccines Research and Development* (known as the International Vaccines Task Force [IVTF]) in response to the urgency of strengthening biomedical research and development (R&D) capacity in low-income countries as a critical success factor for the *Coalition for Epidemic Preparedness and Innovation* (CEPI). The IVTF is tasked with proposing ways national governments and development partners can effectively and sustainably establish and finance vaccine R&D capacity at the national level.

#### Framework:

Following initial teleconferences and a face-to-face meeting on November 10, 2017, IVTF members sought to develop a framework and metrics for biomedical R&D with a focus on clinical trials including vaccine trials. IVTF members further recommended that the Global Health Security Agenda (GHSA) evaluation system be used as a template so that biomedical R&D capacity might be evaluated in the GHSA framework. The GHSA evaluation tool [68] uses three colors with a total of five levels (Table 1). There are 19 GHSA indicators; some, such as *national laboratory system*, *real time surveillance*, and *workforce development*, are relevant to biomedical R&D, but GHSA currently does not include clinical trials capacity, either in the country evaluations or as a development goal. Each of the 19 GHSA indicators includes from one to five sub-indicators.

Table 1. GHSA color scoring system

Score	Color	Description	
1	Red	No capacity	Attributes of a capacity are not in place
2	Yellow	Limited capacity	Attributes of a capacity are in development stage (some are achieved and some are undergoing; however, the implementation has started)
3	Yellow	Developed capacity	Attributes of a capacity are in place; however, there is the issue of sustainability and measured by lack of inclusion in the operational plan in National Health Sector Planning (NHSP) and/or secure funding
4	Green	Demonstrated capacity	Attributes are in place, sustainable for a few more years and can be measured by the inclusion of attributes or IHR (2005) core capacities in the national health sector plan

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<sup>68</sup> . <https://www.ghsagenda.org/assessments#evaluations>

5	Green	Sustainable capacity	Attributes are functional, sustainable and the country is supporting other countries in its implementation
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### Metrics:

We examined the current number of active clinical trials per country in sub-Saharan Africa as a benchmark to develop metrics for clinical research capacity (Table 2). Eighteen countries have 0-5 active clinical trials, 12 countries have 6-10 trials, 14 have 11-50 trials, and six countries have more than 50. Additional work may be completed to examine the subsets that are randomized controlled clinical trials, those relevant to development of vaccines and other pandemic countermeasures, trials by phase, and trials conducted under conditions of an international licensing body such as the European Medicines Agency or the U.S. Food and Drug Administration.

Table 2. Number of active clinical trials in clinicaltrials.gov by country, sub-Saharan Africa – 2017

Cape Verde	0	Togo	4	Botswana	17
Comoros	0	Congo	6	Mozambique	17
Djibouti	0	Guinea	6	Cameroon	19
Eritrea	0	Mauritius	6	Dem Rep of Congo	22
Mauritania	0	Niger	6	Burkina Faso	23
Sao Tome/ Principe	0	Swaziland	6	Mali	27
Seychelles	0	Lesotho	7	Ghana	30
Somalia	0	Sierra Leone	7	Ethiopia	33
Western Sahara	0	Gambia	9	Zimbabwe	35
Angola	1	Guinea-Bissau	9	Nigeria	48
Central African Rep.	1	Liberia	9	Zambia	52
Chad	1	Benin	10	Malawi	63
Equatorial Guinea	1	Gabon	10	Tanzania	65
Madagascar	1	Sudan	12	Uganda	112
Namibia	1	Rwanda	14	Kenya	114
Burundi	2	Senegal	14	South Africa	549
Réunion	2	Côte d'Ivoire	16		

Note: To be updated with results from WHO International Clinical Trials Registry Platform (ICTRP)

<http://www.who.int/ictrp/search/en/>

From this benchmark metric, a preliminary scoring system for clinical research capacity can be developed (Table 3).

Table 3. Preliminary scoring system for national clinical research capacity

Score	Color	Description	Preliminary proposed metric
1	Red	No capacity	Little or no capacity to conduct clinical research; little or no national commitment to develop capacity
2	Yellow	Limited capacity	Limited capacity to conduct clinical research; national interest and intention to develop a conducive environment for clinical research
3	Yellow	Developed capacity	Developed capacity to conduct clinical research, with limited domestic capacity to conduct clinical trials, mainly with external support
4	Green	Demonstrated capacity	Demonstrated capacity to conduct clinical research, including clinical trials under international licensing conditions, mainly under external partnerships
5	Green	Sustainable capacity	Sustainable capacity to conduct clinical research and clinical trials under international licensing conditions with in-country nationals as principal investigators and direct funding recipients, supporting other countries in implementation

As an additional step, sub-indicators can be developed to identify the core elements to guide country biomedical research capacity building. Several potential sub-indicators are listed in Table 4. Additional work by subject matter experts is needed to refine each potential sub-indicator. Additional work also needed to harmonize the framework, metrics, and sub-indicators with previous efforts to develop organizational and national metrics of biomedical research capacity [<sup>69</sup>, <sup>70</sup>].

Six potential sub-indicators are listed. To be consistent with other GHSA indicators, the number of sub-indicators should be no more than five. There may be need for a short list of  $\leq 5$  sub-indicators to be consistent with GHSA and a longer list for more detailed assessments and development of road maps for country capacity building.

**Regulatory:** Criteria and a tool have been developed by the World Health Organization (WHO) for National Regulatory Authorities to evaluate their compliance with the functions they must fill as regulators of drugs and biological products [<sup>71</sup>]. Percentage implementation of indicators are specified for each level.

**Good Clinical Practice:** The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of drug registration. The ICH Good Clinical Practice

<sup>69</sup>. Planning, monitoring and evaluation framework for research capacity strengthening (2016) by ESSENCE on Health Research. [http://www.who.int/tdr/publications/Essence\\_frwk\\_2016\\_web.pdf](http://www.who.int/tdr/publications/Essence_frwk_2016_web.pdf)

<sup>70</sup>. Kirigia JM, Ota MO, Senkubuge F, Wiysonge CS, Mayosi BM. Developing the African national health research systems barometer. Health Res Policy Syst. 2016 Jul 22;14(1):53.

<sup>71</sup>. PAHO/WHO. System for Evaluation of the National Regulatory Authorities for Medicines, Standardized evaluation procedure (2010) <http://www1.paho.org/hq/dmdocuments/2010/POS-EvaluacioRES1.pdf>



(GCP) Guideline, last amended in 2016, describes the responsibilities and expectations of all participants in the conduct of clinical trials, including investigators, monitors, sponsors and IRBs [<sup>72</sup>].

**Laboratory:** Curricula and checklists have been promulgated to develop and assess laboratory capacity for clinical trials (Good Clinical Laboratory Practice [GCLP]) [<sup>73</sup>, <sup>74</sup>].

**Community participation:** International standards for community participation (Good Participatory Practice [GPP]) in biomedical research have been established for HIV [<sup>75</sup>] and for emerging infections [<sup>76</sup>].

**Data management:** The international Society for Clinical Data Management has developed guidelines for Good Clinical Data Management Practices (GCDMP) [<sup>77</sup>].

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<sup>72</sup>. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Efficacy Guidelines: Good Clinical Practice (2016). <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>

<sup>73</sup>. World Health Organization, Special Programme for Research and Training in Tropical Diseases (2009). Good clinical laboratory practice (GCLP). Available at: <http://www.who.int/tdr/publications/documents/gclp-web.pdf>

<sup>74</sup>. National Institute of Allergy and Infectious Diseases (2013). DAIDS Guidelines for Good Clinical Laboratory Practice Standards. Available at: <https://www.niaid.nih.gov/sites/default/files/gclp.pdf>

<sup>75</sup>. UNAIDS/WHO. Ethical considerations in biomedical HIV prevention trials. Geneva, 2012. Available at:

[http://files.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399\\_ethical\\_considerations\\_en.pdf](http://files.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf)

<sup>76</sup>. World Health Organization. Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP). WHO Press, Geneva; 2016. Available at: <http://www.who.int/blueprint/what/norms-standards/GPP-EPP-December2016.pdf?ua=1>

<sup>77</sup>. Society for Clinical Data Management. Good Clinical Data Management Practices (GCDMP), 2013. Available at: <https://www.scdm.org/publications/gcdmp/>

Table 4. Preliminary sub-indicator scoring system for national clinical research capacity

Score	Color	Description	Potential sub-indicators					
			Ethical review	Regulatory <sup>71</sup>	Human resources <sup>72</sup>	Laboratory <sup>73,74</sup>	Data management <sup>77</sup>	Community participation <sup>75,76</sup>
1	Red	No capacity	[TBD from WHO]	Does not meet certain drug health regulation functions	No clinical research sites	No laboratories conducting clinical research	No clinical research data management	No clinical research with community participation
2	Yellow	Limited capacity	“	Meets certain drug health regulation functions	≥1 clinical research site	≥1 laboratory conducting clinical research	≥1 site managing clinical research data	≥1 site conducting clinical research with community participation
3	Yellow	Developed capacity	“	NRA performs certain WHO-recommended functions	≥1 site conducting clinical research to GCP standards	≥1 site conducting clinical research to GCLP standards	≥1 site conducting clinical research to GCDMP standards	≥1 site conducting clinical research to GPP standards
4	Green	Demonstrated capacity	“	NRA improving performance of certain WHO-recommended functions	≥2 sites conducting CT for intl. licensing to GCP standards	≥2 laboratories conducting CT for intl. licensing to GCLP standards	≥2 sites conducting CT for intl. licensing to GCDMP standards	≥2 sites conducting CT to GPP standards and community participation research with national co-investigators
5	Green	Sustainable capacity – <i>with nationals supporting other countries' implementation in each area</i>	“	NRA performs WHO-recommended functions	≥2 sites conducting CT for intl. licensing to GCP standards with national PIs	≥2 laboratories with national leadership conducting CT for intl. licensing to GCLP standards	≥2 sites with national leadership conducting CT data for intl. licensing to GCDMP standards	≥2 sites conducting CT to GPP standards and community participation research with national PIs

NRA = National Regulatory Authority, PI = principal investigator, CT = clinical trial, GCP = good clinical practice, GCLP = good laboratory practice, GCDMP = good clinical data management practice, GPP = good participatory practice

