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### **Executive summary**

The Joint Global Health Trials funding scheme (JGHT) was established in 2009. It is a partnership of four funders, the UK Medical Research Council (MRC), the Department for International Development (DfID), Wellcome and the Department for Health and Social Care (DHSC). The overall aim of the JGHT is to support the best proposals to generate new knowledge about interventions that promise to contribute to the improvement of health in low- and middle-income countries (LMICs), addressing a major cause of mortality or morbidity.

The funders commissioned an external review to understand the impact of the JGHT scheme, its potential for future impact and to inform the design of future funding programmes. The review was carried out by Technopolis from October 2018 to October 2019, information by desk research, database analysis, and consultations through surveys and interviews with Principal Investigators (PIs), coinvestigators, and global health experts and funders ('Key opinion leaders').

The evidence reviewed demonstrates that the JGHT is delivering on its core aim and has achieved tangible outcomes and impacts: JGHT-funded research has generated new knowledge about interventions which in turn are starting to contribute to improving health in LMICs.

#### Overview of the JGHT portfolio

The scheme includes two strands of funding through annual calls: *Full trial awards*, which support late-stage and health intervention trials (Phase III/IV) to evaluate efficacy and effectiveness, and – starting from Call 5 – *Development awards*, which enable studies to carry out formative work preparing for a full trial.

In Calls 1-7, the JGHT scheme funded a portfolio of 63 full trial and 33 development awards (of which 28 and 22 had closed by June 2019, respectively), representing an investment of £138.8m. Research addressed a broad range of health issues, with strong emphasis on infectious diseases in the earlier calls, and an increase in mental health research from Call 5. Trial sites are located in 47 countries; 75% of trials include sites in Africa, 30% of trials have sites in Asia, and 8% in Central and South America.

The largest share of full trial awards (63%) were led by principal investigators (PIs) affiliated with institutions located in high-income countries (HICs), compared to 13% of awards led by researchers from LMIC institutions and 24% led by researchers at 'joint units' (programmes or institutes funded by organisations from HICs located in LMICs<sub>1</sub>). Around one third of awards was led by female PIs.

The majority of PIs engaged with policy makers during the design and/or implementation of the project (87% of PIs of full trials and all development awards surveyed). 39% of PIs interviewed had engaged with community groups and advisory boards, community leaders, and individuals such as patients who shared their experiences. Several researchers highlighted the importance of joint units in this respect, as these have established engagement structures which researchers are able to draw on.

### The JGHT is delivering against its policy and health objectives

Research funded by the JGHT has influenced policy and led to health outcomes.

Of the 28 closed full trial awards, 32% have resulted in policy influence, and a further 36% have a high potential for success, based on the trials' findings and the level of stakeholder engagement by the study team. Three of these trials provided important evidence by informing decisions to *not* change a policy or implement an intervention. In addition, three active full trials have already influenced policy. Policy outcomes included direct influence on the World Health Organisation (WHO) guidelines; addition of

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<sup>&</sup>lt;sup>1</sup> Joint units include: KEMRI Wellcome Trust Research Programme, Kenya; Mahidol Oxford Research Unit, Thailand; Malawi-Liverpool-Wellcome Trust Clinical Research Programme, Malawi; Mwanza Interventions Trials Unit, Tanzania; MRC Unit The Gambia; MRC/UVRI Uganda Research Unit, Uganda; Oxford University Clinical Research Unit, Vietnam.

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products to the WHO Essential Medicines list; influence on WHO policies in other ways, e.g. lending confidence to a guideline under scrutiny, uptake into a best practice strategy paper; influence on national policies; and influence on strategy of international donors and shifting funding priorities.

Nine full trials and one development award likely led to the implementation of a health intervention. Four interventions were recommended by WHO guidelines, at least two of which have been purchased by governments via the Global Fund. Four further interventions have been, or are starting to be, implemented by national governments as part of public health programmes. One intervention is being implemented by an NGO with support from the national government.

In addition, the implementation of JGHT-funded research itself has led to direct and indirect benefits, e.g. through improved standard of care and access to care, education and awareness, for study participants and the wider community. For example, two trials alone have led to direct health benefits for around 450,000 trial participants.

Four key enablers of policy and health outcomes arising from JGHT-funded research were identified:

- 1. The topic of the trial is timely and under debate in the policy arena, and hence key policy makers have strong interest in the research evidence.
- 2. The trial addresses a neglected health issue, and little research evidence was available before the trial. The trial thus substantially increased the level of robust evidence on which to base policy decisions.
- 3. Collaboration with policy makers and key stakeholders in the health system during research planning and implementation, e.g. by embedding the trial within local health programmes.
- 4. Active engagement with policy makers to inform and influence relevant policies. This is facilitated by researchers holding advisory functions, e.g. as members of guideline committees, or key policy makers holding advisory functions related to the research, e.g. as members of the trial steering committee.

### The JGHT is funding high-quality research, leveraging additional funding, building capacity, and fostering collaboration

The majority of the 28 closed full trial awards have either published the main trial findings<sup>2</sup> (20), submitted them for review (3), or are in the final analysis stage, indicating a high trial completion rate of 89%. 60% of JGHT awards reported on ResearchFish® that they had received substantial additional funding (co-funding and follow-on funding), capturing around £160m in total. Most of this funding was provided by Wellcome, EDCTP, NIHR, BMGF and US NIH<sub>3</sub> (in order).

Of 22 closed development awards funded so far, at least 23% have led to full trials - one funded by the JGHT, and four by other funders, including DfID, US NIH and EDCTP.

JGHT-funded research has built capacity, in HICs and LMICs, and fostered collaboration. 82% of coinvestigators from full trial and development awards (140 of 170) felt that the JGHT-funded project had positively impacted their scientific knowledge, and 50% indicated their knowledge of local health needs had improved. Publications of main findings of full trial awards named investigators affiliated with 106 distinct institutes; over half of these institutions were located in LMICs (57), indicating a high level of involvement in the delivery of the trials. The lead authors of a quarter of publications (27%) were based at LMIC institutions, comparable to the shares of lead authors affiliated with joint units (31%), and institutions in HICs (27%). JGHT awards have also led to new collaborations (e.g. as reported by 50% of co-investigators) and allowed researchers to start participating in collaborative networks (30%).

<sup>2</sup> i.e. relating to the primary outcome of the trial

 $_3$  European & Developing Countries Clinical Trials Partnership; National Institute for Health Research; Bill and Melinda Gates Foundation; US National Institutes of Health

### The design and promotion of the JGHT are appropriate

Researchers and key opinion leaders were predominantly positive regarding the design and promotion of the JGHT, and no major issues emerged in the consultation. A range of additional activities were highlighted by PIs and co-investigators which the JGHT could support to help it achieve its aims. These included funding for training and other types of research such as implementation and laboratory studies; dissemination and knowledge exchange. Key opinion leaders highlighted the potential for additional support for applicants from LMICs. While researchers appreciated the 'light-touch' monitoring arrangements, many researchers felt that reporting beyond ResearchFish® should be put in place to improve tracking of outcomes and impacts.

Of PIs who described a weakness, 29% considered the amount of funding available insufficient, both in terms of the size of awards and the lack of funding for additional aspects such as dissemination, capacity building or student fellowships (e.g. as provided by the EDCTP and US NIH). Despite the fact that the JGHT calls for proposals do not state a budget or time limit, comments by several researchers indicated that the JGHT is perceived to provide funding of about £2-3m for a duration of 3 years.

#### The partnership of JGHT funders provides added value

The partnership of JGHT funders is working well. It has resulted in a variety of benefits to both funders and researchers, such as the ability to pool budgets and de-risk investment, closer cooperation and sharing of expertise between funders, and a de-fragmentation of the funding landscape. The partnership is considered to have helped maintain the UK's international leadership in producing high quality research of relevance to LMICs. However, international funders consulted were not aware of the scheme.

### The JGHT represents value for money (VfM) in a variety of ways, thereby maximising the impact of the investment

The JGHT represents value for money (VfM) in a variety of ways, maximising the impact of the investment by its funders. The scheme is acknowledged to fill a gap in the global research landscape and delivers research with strong relevance to health issues of disadvantaged populations in LMICs. This is achieved through a partnership of funders, leading to sharing of expertise and risk and to efficiency gains. Its flexible scheme management approach has enabled trials to complete and thus avoid 'research waste', leading to 89% of closed awards completing trials and publishing their main results. The value generated by the JGHT includes scientific knowledge and capacity, which has contributed to further scientific work and strengthened the wider research ecosystem. In addition, financial benefits have already been achieved or are anticipated based on current award monitoring data:

- Research cost savings achieved from development awards de-risking full trials
- Additional research funding leveraged on the basis of the JGHT award
- Anticipated cost savings for LMIC health systems and improved health outcomes, partly due to increased education and awareness of health issues
- Direct employment effects of researchers, trial staff and supply chains for the UK and LMIC.

### Recommendations to increase the value gained from JGHT-funded research

The review concluded that the JGHT is delivering on its core aim and has achieved tangible outcomes and impacts. Underpinned by the evidence gathered, five recommendations to further increase the value gained from the JGHT-funded research have been developed:

- Keep the overall design of the JGHT, but clearly communicate the scheme's award parameters to
  potential applicants, and re-focus researchers on applying for appropriately sized budgets to answer
  the research question (rather than fitting to the perceived funding envelope).
- 2. Provide additional support for stakeholder engagement, both pre- and post-award, to avoid challenges during trial implementation and enable pull-through of research findings into policy and practice. This could include small grants for 'partnership workshops' and/or an expansion of the

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development award scheme, as well as additional funding to cover engagement activities after the award has closed. Funders should explore options for how to maximise opportunities for dissemination and engagement for findings with high potential for policy influence and health impact. This could involve taking an active role in these efforts, e.g. by targeting media and convening meetings, or providing support for a team of specialists for this function.

- 3. Increase support for LMIC researchers, including resources to assist with proposals, providing detailed feedback to unsuccessful LMIC applicants, promotion of JGHT calls in LMICs, and 'match-making' activities to facilitate access to expertise and infrastructure.
- 4. Agree on key criteria for project selection among JGHT funders, defining how to balance between the size of the health need addressed, the risk of interventions tested not proving effective, and the likelihood that a trial leads to policy influence and health outcomes.
- 5. Launch additional project monitoring, enabling better tracking of progress and outcomes and identify options to support dissemination of findings and engagement with policy makers.