KEY ACTIONS for good participatory practices in trials of emerging (and re-emerging) pathogens – GPP-EP (section references are to the WHO GPP-EP guidelines)	WHO SHOULD TAKE THE LEAD	HOW LONG THIS MAY TAKE?
1. DURING STUDY DESIGN SELECTION AND PROTOCOL WRITING PERIOD		
Become familiar with any social and cultural elements that can be relevant to implementation of the trial (see Section 4.1 Formative Research). Engage an anthropologist or expert in community participation with field experience in the study area. Describe social context of the priority communities, including main issues raised in community relationships with outbreak response teams; channels of communication and decision-making; socio-cultural norms, practices, and traditions; language(s); and other elements relevant to the study.	*Sponsor and Principal investigators*	*One month*
Adjust the protocol and SOPs to ensure they are adapted to knowledge of local community societal structures and relationships with the health sector (see Section 3 Guiding principles and benchmarks). Keep SOPs simple but ensure that they provide field staff with clear instructions on the desired approach with trial stakeholders, including the community and study participants.		
2. BEFORE THE TRIAL STARTS		
Develop a succinct (and evolving) stakeholder engagement plan (see Section 4.2 Stakeholder engagement plan) Discuss formally or informally with communication experts, social mobilisers, anthropologists, and other key informants the perceived main obstacles to the study. Further describe potential negative developments/experiences, community resistance to actions by health sector actors, and community preoccupations regarding the implementation of public health measures to control the outbreak. Identify the range of stakeholders to be engaged at local, national, regional, and international level (including governmental, non-governmental, and community-based organisations and groups) and clarify the type of engagement appropriate for each stakeholder, e.g. being informed, consulted, collaborated with, or emancipated to make decisions. Describe methods for resolution of differences of opinion. Determine strategies for the establishment, purpose/scope, and maintenance of stakeholder advisory mechanisms, including for a community advisory board. If a functioning CAB will not be formed, document the reasons. Determine what education is needed to enhance stakeholder understanding and support effective engagement with a planned	*Sponsor and Principal investigators*	*One month*

trial over its life-cycle. Keep your stakeholder engagement plan simple and to the point. Maintain clear records of discussions and agreements with relevant stakeholders.		
Develop a succinct (and evolving) operational communication and issues management plan (see Section 4.3 Communications and issues management plan) Develop a plan to support open channels of communication through the trial's life-cycle that describes diverse stakeholder information needs from early phases of stakeholder engagement to recruitment, enrolment, trial closure, and results dissemination, including timelines for disseminating information and procedures for promptly addressing inquiries. Prepare and disseminate frequently asked questions and answers (FAQs) regarding the trial objectives, rationale, and operations. Share these with all trial staff, underscoring that the trial has received national approval and respects the rule of law. Meet with local and national authorities to explain the trial objectives, clarify their doubts, and answer their questions. Request an official letter of support from national authorities. Encourage local authorities to maintain a constant dialogue with national authorities and the research coordination team, supporting investigators to concentrate their efforts on priority communities and potential participants in a way that is receptive, reactive, and adapted to the epidemic dynamics. Harmonise the trial's plan with those of national and local response coordination bodies and agree on the frequency of updates as well as mechanisms for urgent communication with politicians and Ministry of Health personnel who may be called upon to explain the trial at any time. List all identified issues that could emerge and undermine the trial success before, during, or after trial completion and detail the process for developing key messages, question and answer briefing notes, and other materials created to address concerns. Designate key trial staff responsible for addressing urgent issues and establish the chain of communication for crisis management within the research team and with relevant stakeholders. Engage one or more national 'champions' who will publically support the trial (e.g. a national authority, a religious leader, a senior health expert), ensure their full understanding of the trial objectives and operations, and keep them informed at all times.	*Sponsor and Principal investigators* *National, local authorities/ Communities*	*One month*
Incorporate the stakeholder engagement plan in all aspects of trial preparation (see Section 1.6 Understanding, implementing, and monitoring GPP-EP). Ensure that sufficient human, logistic, and financial resources are available before launching activities to ensure optimal	*Sponsor/* *Principal investigators*	*One week*

participatory approaches throughout trial conduct. Require that GPP-EP plans are explicit in all formal protocols and that implementation of the GPP-EP guidelines is monitored, with process and outcomes documented.	*National authorities, academic institutions, ethics committees, institutional review boards, and community stakeholders.*	
Set up optimal trial conduct: study research team, coordination and communication structures, and administrative /logistics systems (see Section 4.8 Trial accrual, follow-up, and exit) Recruit and train local investigators and field workers who represent the diversity of the priority study areas and have the necessary technical capacities, knowledge of strategic local actors, and understanding of the local context. Identify and engage local people who are good communicators, are recognised to be honest, are social mobilisers or can play that role, and are trusted or best placed to be trusted by local communities to provide input into the evolving stakeholder engagement plan. Ability to speak local languages is an obvious asset for communicating effectively about the trial objectives, rationale and operations to communities and potentially eligible persons. Set up a coordination structure, field supervision mechanisms/tools, and an effective communication system for multitasking teams that will conduct the trial, as per GCP standards while following GPP-EP guidelines, to ensure both professional trial conduct and the meaningful involvement of trial communities. Anticipate needed tools and equipment (cars, kits, cold chain, etc.) before launching a pilot phase, excluding all equipment with potentially symbolic value that could potentially generate resistance (e.g. logos). Prepare a pilot phase to test the system, documenting what worked and what did not. Share lessons learned immediately with all team members and adjust SOPs for stakeholder engagement and key messages.	*Principal investigators* Principal investigators, study coordinators, field team leaders *Logistic/ administration*	*Recruitment:* *2 weeks* *Training:* *1 week* *1 month* *1 week* *1 month*
3. DURING TRIAL IMPLEMENTATION		
Obtain community consent prior to implementation of activities in priority communities (see Section 4.4 Protocol development)	*Trial sponsors provide time and*	*1 month*

Identify community dialogue facilitators and provide opportunities for local stakeholders, in particular community stakeholders, to contribute in a timely fashion to decisions about trial design issues and procedures, including the products to be tested, trial objectives, recruitment strategies, informed consent materials and procedures, reimbursement policies, counselling approaches, follow-up procedures, and post-trial access to trial products or procedures. Organize public meetings or workshops to explain the study protocol after identifying and sensitizing community opinion leaders who are respected and trusted by the community and can participate actively in meetings/workshops. Pay particular attention to strategies to explain eligibility criteria (randomization, exclusion, etc.). Ensure that all members of field teams understand the importance of demonstrating respect for the study communities, taking the time to clearly and truthfully answer questions and address concerns, and accepting delays if the communities need more time to discuss.	*resources for local research teams*	
Monitor implementation of the trial communication and issues management plan. (see Section 4.3 Communications and issues management plan) Document the current and evolving social, political, economic, and epidemiological national and local context. Adapt the communication strategy as the context evolves and disseminate information through stakeholder advisory mechanisms and other means to study communities and study participants. Regularly review the notes for the record from formal and informal meetings of trial stakeholders to identify new issues, possible solutions, and responses to previously-raised issues. Produce specific communication tools in response to issues of importance that arise (ex: written Fatwa giving advice from religious authorities about immunization during Ramadan). Maintain clear written records of discussions, agreements, communication activities, and all issues that emerge, how they are responded to, and their outcome. This includes relevant stakeholder recommendations, actions taken by the research team, and any unresolved issues that require further follow-up.	*Principal investigators* */field teams/community liaison staff/ social mobilisers /media experts*	*All along the study*
Implement the trial stakeholder engagement plan (see 4.2 Stakeholder engagement plan) Determine stakeholder advisory mechanisms and appropriate construction of the trial's community advisory board with relevant stakeholders, including terms of reference and functioning (Section 4.2.C.4). Monitor continuously the trial's community engagement approach and modify readily, and as needed, communication and engagement approaches, as well as methods or equipment that might bear a symbolic significance that could generate community	*Principal investigators* *authorities /* *field investigators/*	*All along the study*

resistance. If community resistance emerges, identify and characterize it, determine its source, and act with the community advisory board members, other stakeholder engagement mechanisms, and community mobilisers and communicators to resolve the issue generating community resistance. This can include directly working with those at the source of the rumour to understand its origins, dissipate any misunderstanding, and engage them in actively countering the rumour.	*CAB members/* *community liaison staff/* *social mobilisers*	
Adapt your community engagement approach to all audiences, making scientific information accessible to all and ensuring that every trial participant understands the trial. Ensure that field teams express respect and act professionally to build a trusting relationship with trial participants and to reassure them and the community that the trial safety and biosecurity measures guarantee participant and community security. Use low-profile interactions, such as small groups, minimal number of cars, and parking in a discrete location, so as not to disturb the population. Incorporate and sustain relevant messaging in a continuous communication process addressing specific audiences throughout the study, including for study participants to support their ongoing informed consent and regular study participation in follow-up visits. Ensure that community liaison staff have telephones and other communication equipment readily available to support two-way communication from the field about concerns arising.	*field investigators/* *social mobilisers* *community liaison staff*	*All along the study*
Obtain informed consent from each participant (see Section 4.5 Informed consent process) Work with relevant stakeholders to develop locally acceptable, effective informed consent procedures and materials. Discuss the following topics with community stakeholders during development of the informed consent materials and procedures: who to consult further about informed consent processes, local cultural practices that may affect decision-making, literacy level, languages spoken, legal and local forms of identity, definitions of 'minor', capacity to give consent, any reimbursement for travel/time, protection of rights, methods to test comprehension, trial-related harm, and preferred ways for the study team to contact participants and for participants to contact stakeholders independent of the research team. Continuously review the informed consent process for any concerns about comprehension or process, including the study's provisions for the confidentiality and security of study information.	*field investigators/community liaison staff*	*1 week*
Establish agreed standards of prevention and care in the trial (see Section 4.6 Standard of prevention and care) Work with relevant stakeholders in establishing the type, scope, and process by which participants are provided with, or referred to services to access, the full prevention package. Review the prevention package regularly, taking into consideration new	*Sponsor and principal investigators*	*1 month*

information, improved education models, and novel risk reduction methods that have shown promise in other prevention trials for the same pathogen. Discuss and agree with relevant stakeholders on the standard of care and treatment for individuals who are identified during the screening process as having acquired the emerging pathogen already and for individuals who acquire the pathogen during the trial. Identify local care and treatment services, local non-governmental or community-based organisations, and survivor support groups; determine their capacities; and seek their views and perspectives in order to design optimal referral mechanisms. Discuss and agree with relevant stakeholders on the care and treatment package, taking into account the trial protocol ethical (minimum) requirements, current national and international care and treatment guidelines and policies, and local provision of care and treatment services. Discuss and agree with relevant stakeholders on the range of ancillary services that can be made available to study participants at the trial site or via referral and reasons for their inclusion or exclusion. Maintain clear written records of discussions and agreements about standard of prevention and standard of care, including relevant stakeholder recommendations; actions taken by the research team; aspects of prevention, care, and treatment that will not be offered and why; and any unresolved issues that require follow-up. Document any changes in standard of prevention or care during trial conduct as this may be important to eventual data analysis and interpretation of trial findings.	*field investigators/* *community liaison staff*	
Establish and communicate about policies on trial-related harm (see Section 4.7 Policies on trial-related harms) Consult relevant stakeholders about possible social harms of trial participation, paying particular attention to individuals or groups who may be vulnerable, marginalised, stigmatized, or who have less power in society and seeking their advice on local expectations about research team obligations to address trial-related harms. Develop strategies to prevent or reduce the risk of trial-related harms, measures to encourage and facilitate their reporting, and methods to investigate events that have been reported indirectly, such as through a third party, taking confidentiality issues into account. Discuss and agree with relevant stakeholders on procedures for ensuring optimal referrals to appropriate services for trial-related harms and any compensation or insurance policies, when applicable, including coverage provided by the policies, how claims are made, and how participants are informed of their rights in relation to the policies.	*Principal investigators/* *National and local authorities/* *Community liaison staff*	

Maintain good interactions throughout trial conduct (see Section 4.8 Trial accrual, follow-up, and exit) Institute trial accrual, follow-up, and exit processes, after discussions with relevant stakeholders, that take into account strategies and messages that are socially and culturally appropriate, that meet the needs of specific stakeholders in terms of language and literacy, and that draw on a range of communication modes, including written, oral, and visual. Discuss procedures to anticipate, monitor, and mitigate trial-related stigma resulting from ineligibility to enrol or from enrolment itself. Establish procedures for training and supervising trial site staff about creating respectful relationships with participants and fostering an environment that is non-judgmental and welcoming. Establish strategies to ensure the confidentiality of participants during trial visits and while following-up participants outside the trial clinic and after trial exit. Adopt procedures for informing participants about trial results and trial product assignment, when available. Determine procedures for transfer of care at the end of follow-up or trial closure, such as providing participants with referrals to ongoing care, supportive services, survivor groups, and cohort studies. Provide relevant stakeholders with high-level summary updates on trial accrual, follow-up, and trial exit processes at agreed intervals, protecting the confidentiality and security of trial participants at all times. Seek advice from relevant stakeholders on how to improve accrual, follow-up and exit processes, and messages. Maintain clear written records of discussions and agreements, including ongoing discussions about ways to modify strategies.	*Principal investigators* *field teams/* *community liaison staff*	*All along the trial*
4. AFTER THE TRIAL		
Managing trial closure (see Section 4.9 on trial closure, results dissemination, and post-trial access to trial products or procedures). Effectively engage relevant stakeholders about trial closure and results dissemination in a transparent manner to build trust and lay a positive foundation for future research, beginning by discussing possible trial closure scenarios early in the research life-cycle. Consult with relevant stakeholders to develop a results dissemination plan, detailing strategies to manage expectations about trial results, planned timelines for trial closure at the site and at other sites, completion of data analyses, and availability of results, procedures and timelines for those who will be informed of trial results in confidence prior to public release, and plans for public dissemination. Ensure that trial participants are provided opportunities to learn trial results before they are announced publicly. Discuss with relevant stakeholders issues of data ownership, data access, and scientific publication, including how the research team will facilitate community stakeholder access to published trial results. Discuss and agree with national governments on responsibilities and funding for licensure requirements and access issues, should	*Sponsor and Principal investigators* */national authorities/* *field investigators/* *relevant stakeholders*	*From start of trial through to completion and publication of findings*

the prevention or treatment product or procedure under investigation be shown to be safe and effective. Discuss with relevant stakeholders expectations about and provisions for possible pre-licensure access, plans for follow-on, open label, cohort studies, or other studies, and how such pre-licensure access will be funded, in the event that a compelling positive result, with no safety concerns, is observed. Develop a clear strategy and funding mechanisms for how a prevention or treatment product or diagnostic procedure will be made available and accessible to participants (at a minimum) rapidly, affordably, and sustainably, should it be shown to be safe and effective.		