Organisational Strategy 2018 – 2022

ISARIC

International Severe Acute Respiratory and emerging Infection Consortium

version: 4
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Table of Contents

List of Figures

Glossary

ALIMA	Alliance for International Medical Action
APPRISE	Australian Partnership for Preparedness Research on Infectious Diseases Emergencies
BARDA	Biomedical Advanced Research and Development Authority
CEPI	Coalition for Epidemic Preparedness Innovations
EDCARN	Emerging Diseases Clinical Assessment and Response Network
EFPIA	European Federation of Pharmaceutical Industries and Associations
GloPID-R	Global Research Collaboration for Infectious Disease Preparedness
InFACT	International Forum for Acute Care Trialists
PREPARE	Platform for European Preparedness Against (Re-) emerging Epidemics
REACTing	REsearch and ACTion targeting emerging infectious diseases
SPRINT-SARI	Short PeRiod IncideNce sTudy of Severe Acute Respiratory Infection
WHO R&D Blueprint	World Health Organization Research & Development Blueprint

FOREWORD

It is easy to forget, yet hard to convey, the enormous weight of pain and suffering caused by epidemic infections. The 2014-2015 Ebola outbreak in west Africa alone caused almost 12,000 deaths and left around 10,000 children without one or both parents[1]. Epidemics of infectious disease are a clear and present threat to health and equity for which we are not adequately prepared.

Following the 2009 influenza pandemic, during which over 40,000 patients received treatments that did not have robust clinical trial evidence of efficacy, and during which no therapeutic trials were completed, a group of clinical researchers came together and formed the International Severe Acute Respiratory and emerging Infection Consortium (ISARIC). Their aim was to find a solution to the repeated failure to gather the evidence from patients, both between and during outbreaks, that is needed to improve patient-care and inform public health responses.

The concept of ISARIC is simple: patient-based research must be at the heart of an evidence-based response to epidemic infections. A grass-roots consortium of clinical investigators is needed to generate the evidence to improve clinical care and public health responses, and to support the development and evaluation of new diagnostics, drugs and vaccines.

ISARIC has achieved much since its inception, having played a major role in clinical research preparedness and in the response to MERS-CoV, Ebola and Zika (see annex 4). The west Africa Ebola outbreak was, however, a watershed, and a new research landscape has emerged in its wake. WHO has affirmed the importance of research as a pillar of outbreak preparedness and response, and there has been an unprecedented commitment to invest in research and development for new diagnostics, therapeutics and vaccines. This aspiration for a better evidence base and for better interventions to reduce the risk and impact of epidemics requires a stable, agile, and proficient network of research partners. The role of local investigators and research networks is therefore more critical than ever.

The time has therefore come for ISARIC to revisit its purpose, functions, and organisation. This document lays out the case for ISARIC and the vision for the next five years. It ensures ISARIC remains focussed on its core business of clinical research, and is a dependable partner for global and national health agencies, as well as for product R&D initiatives.

[1] Source: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)60179-9/fulltext

EXECUTIVE SUMMARY

What's new?

The revised ISARIC strategy reaffirms some core elements of ISARIC, clarifies the role ISARIC aspires to have for its members and external partners, and introduces some changes. The purpose, mission, vision and values of ISARIC have been re-formulated as the tenets that direct ISARIC's organisation and work-plan.

We have defined the menu of 'services' that must be delivered for ISARIC to fulfil its purpose and made a clearer distinction between the services delivered **by** the member networks and those delivered by the ISARIC supporting structures **to** the member networks.

By more explicitly defining what ISARIC stands for and what it can do, the organisational strategy clarifies the added value that ISARIC as a research partnership brings to its members and to global health partners such as WHO.

The governance structure has been re-designed, with a stricter definition of member status and a clearer distinction between strategic and operational responsibilities, introducing a Board of Directors that reflects the global membership and an Executive Director who is focussed on operational tasks.

This strategy will form the basis for re-organising ISARIC's functioning, defining a work-plan and goals, and seeking and securing financial resources to deliver our mission and vision.

Changing international landscape in clinical research preparedness and response

Since ISARIC's inception in 2011, the need for more intensified and coordinated research in the area of health emergencies has led to the establishment of several global initiatives such as CEPI, EDCARN, GloPID-R and the WHO R&D Blueprint. This changing international landscape, of increased coordination, collaboration and investment, requires an equal response from the international clinical research community. This strategy is part of that response, and defines the role that ISARIC aspires to have, by its members and for its members.

Our purpose, mission and vision

Our purpose	To prevent illness and deaths from infectious diseases outbreaks.
Our mission	To generate and disseminate clinical research evidence for outbreak-prone infectious diseases, whenever and wherever they occur.
Our vision	A global federation of clinical research networks, providing a proficient, coordinated, and agile research response to outbreak-prone infectious diseases.

Our values

ISARIC's values that are fundamental to what we do and how we should work together and interact are:

Collaborate globally	Effective clinical research on infectious diseases demands global collaboration.
Act locally	Clinical research on outbreak-prone infectious diseases should be driven by those with understanding of the patients and populations at risk, and should build on an adequate local clinical research capability.
Uphold collegiality	We build trust by acknowledging each other's contributions and by building our decisions on open and fair discussion.
Maintain agility	We are capable of rapidly adapting our activities to the changing contexts of outbreaks.

Our mission-oriented goals and services

ISARIC, as the synergistic sum of all its Members has three organisational goals in pursuit of its mission:

Clinical research	To generate the best possible clinical evidence both between and during outbreaks through clinical research conducted by ISARIC Members.
Capacity building and support	To empower locally-led research by building clinical research capabilities and by providing urgent 'research response' support when needed.
Communication and Dissemination	To make clinical evidence, expert opinion, experience and tools available to those who need it, whenever they need it.

Services by ISARIC members in pursuit of these mission-oriented goals include:

- The design, execution and evaluation, and reporting of clinical research studies (e.g., clinical observational studies and phase II-III clinical trials).
- Capacity building activities ranging from ad-hoc mentoring of individual researchers to the design and implementation of long term capacity development programmes, including at regional levels. When needed and requested, the provision of research response support to enable locally-led urgent research.
- Disseminating the clinical evidence generated by ISARIC and other available expert experience, knowledge and tools to stakeholders (e.g., healthcare providers and health emergency responders, government public health authorities and regulators), in a timely and unrestricted fashion.

Our vision-oriented goals and services

These three mission-oriented goals are complemented by three internal, vision-oriented goals and services that together provide the rationale for ISARIC.

Collaboration	To build and maintain an up to date membership and initiate and implement joint collaborative multi-Member Projects that transcend the geographic and disciplinary boundaries of our Members.
Interoperability	To globally unlock, mobilise and connect the experience, knowledge, data and information and resources of our Members.
Acceleration	To accelerate the initiation and completion of clinical research by our Members (and others).

Services provided within ISARIC to our Members include:

Project Initiation & Design	Initiating and designing joint clinical research projects ranging from observational studies and clinical trials, to large-scale multi-centre studies.
Project Management	Supporting funding application development, progress monitoring and reporting, contract management, financial, legal and contractual support and communications.
Scientific and Technical support	Providing scientific and technical support and advice when research capabilities are missing, or in complex emergencies.
Networking & Knowledge Sharing	Expanding capacity in Low and Middle Income Countries (LMICs). Organising and facilitating-meetings around specific topics of interest. Facilitating interactions between clinical scientists on behalf of key global health stakeholders such as WHO Providing access to web-based knowledge sharing platforms and programmes.
Standardisation and Harmonisation	Developing and disseminating harmonized and standardized tools, methodologies, systems (e.g. research protocols), processes (e.g. data sharing policies) to promote interoperability.
Research Innovation	Developing, testing and validating innovative approaches and methodologies that speed up the process of clinical research by addressing factors that delay the process of starting and conducting clinical research.

Governance

ISARIC will re-design its organisational structure. We will move towards a research partnership model consisting of a federation of clinical research networks, with a clear relationship to major international stakeholder organisations, such as WHO.

The structure will strike a balance between the need for coordination across the member networks and the need for autonomy of the member networks. The Members are represented in a Member Assembly, which elects the Board of Directors, responsible for implementing the ISARIC strategy. An Executive Director will be appointed who will be responsible for coordinating the delivery of the services to the members. The Directors are supported by an operational Global Support Centre, embedded in the professional academic environment of a GSC Host Institution.

The two current external Advisory Boards - the Independent External Advisors and the Stakeholder Advisory Board – are to be combined into one single Advisory Board.

ISARIC will explore the possibility of establishing ISARIC as a legal entity. By establishing an independent legal entity, ISARIC can develop its role as an international federation, with singularity of purpose, being accountable to its Members and able to enter contractual relationships with its stakeholders, independent from the GSC Host Institution.

The ISARIC organisational strategy will form the basis for the Annual Plan that sets the annual agenda for ISARIC and contains concrete targets for ISARIC Projects.

Priority actions

The priorities in 2018 to execute this revised strategy are, in no particular order:

- Implement reorganisation of the governance structures.
- Agree an operational model for interaction between ISARIC and strategic stakeholders such as WHO.
- Secure funding to appoint an Executive Director and to strengthen capability to deliver core services.
- Prepare a 2018-2019 work-plan in collaboration with members and strategic stakeholders.

1. INTRODUCTION

The international landscape of actors within clinical research preparedness and response can be divided crudely into three groups as depicted in figure 1.

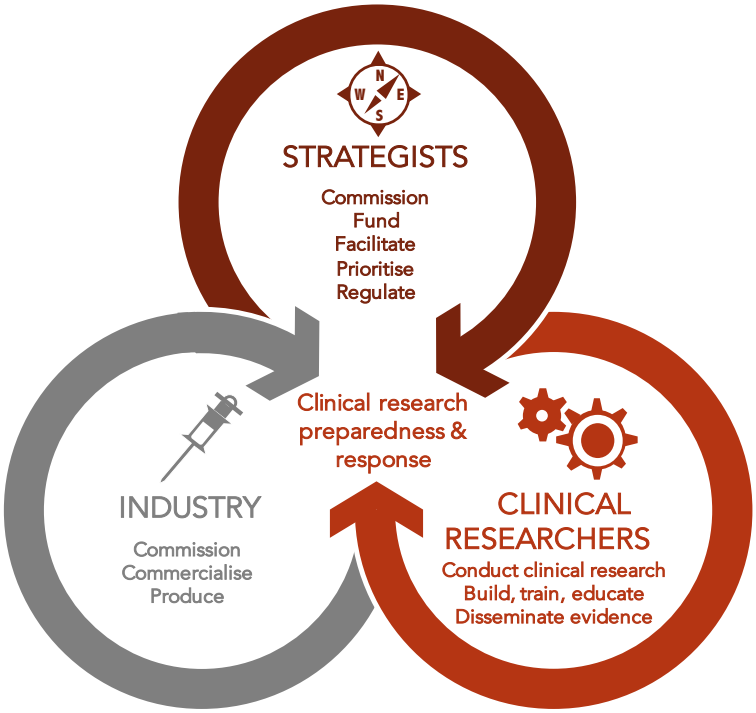


Figure 1: Actors in clinical research preparedness and response

Health authorities and government and charitable funding organisations comprise the 'Strategists', commissioning, funding, facilitating, prioritising and regulating clinical research in infectious diseases. This group consists of organisations such as WHO, the European Commission (DG Research, DG Santé and its executive agencies), the Wellcome Trust, the Bill & Melinda Gates Foundation, and BARDA.

Industry, comprising of private sector pharma, biotechnology and medtech companies form the second group. They conduct in-house R&D, commission clinical research, and produce and commercialise vaccines, diagnostics and therapeutics.

The third group are the independent Clinical Researchers, that conduct clinical research to generate new knowledge and to develop, evaluate and implement improved preventive, diagnostic, and treatment strategies. This group includes a myriad of small and larger clinical research networks including APPRISE, InFACT, PREPARE, REACTing, and the three EU funded Zika consortia to name a few.

Since ISARIC's inception in 2011, the need for more intensified and structural international coordination and collaboration has gained momentum amongst the Strategists and Industry. This has led to the establishment of several global initiatives such as CEPI, EDCARN, GloPID-R and the WHO R&D Blueprint. This changing international landscape, of increased coordination and collaboration, requires an equal response from the international clinical research community, to ensure there is a clear and complete pathway from bedside to bench and back. Provision of the operational capabilities to conduct clinical research, whenever and wherever needed, is the role that ISARIC aspires to have, by its members and for its members.

2. AMBITION

This section describes the ambition of ISARIC consisting of its Purpose, Mission, Vision and Values. Together, they are the foundation of ISARIC and provide its overall inspiration, rationale and direction.

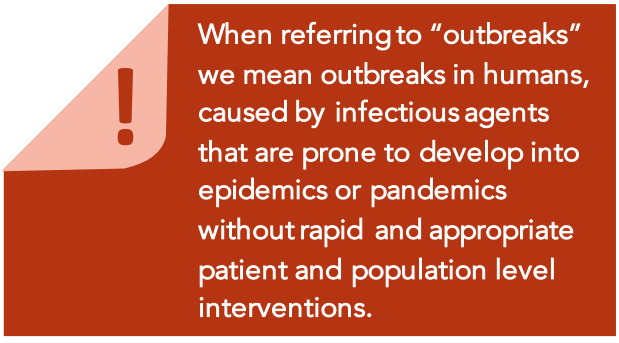
2.1 Purpose, Mission and Vision

Our purpose: To prevent illness and deaths from infectious diseases outbreaks.

The purpose of ISARIC is to reduce the morbidity and mortality caused by outbreak-prone infectious diseases.

Our mission: To generate and disseminate clinical research evidence for outbreak-prone infectious diseases, whenever and wherever they occur.

When outbreaks occur, local healthcare professionals and public health authorities need quick and unrestricted access to the best available clinical evidence to guide their decisions on the optimal prevention, treatment and control strategies at a patient and population level. The longer such information is unavailable or incomplete, the higher the risk that outbreaks develop into epidemics or even pandemics, with potentially devastating consequences. The generation of such clinical evidence requires clinical research studies to collect and analyse patient data and samples. The R&D pipelines for new diagnostics, therapeutics and vaccines for epidemic infections also require timely access to clinical data and samples for the development of new countermeasures and for their evaluation in clinical trials.



Time is of the essence in initiating clinical research studies at the scale needed to have an impact. Designing and implementing such clinical research is however a complex endeavour, especially in low-resource settings. It is complex and challenging for a variety of reasons, including the unpredictability of the timing and magnitude of outbreaks, the extremely short time frame for conducting clinical research (including the short duration of clinical illness and of outbreaks), the tendency for outbreaks to occur in resource-poor settings, the potential that the outbreak itself disrupts delivery of healthcare and societal functioning, and the fact that the patients and their biological samples may pose a significant risk to healthcare and laboratory workers. In addition, market-driven models of clinical research fail in

the uncertain circumstances surrounding outbreaks, with epidemic infections having been described as 'a volatile market'.

These factors, combined with a shortage of stable and flexible sources of research funding, make it extremely difficult for individual investigators or institutions to deliver meaningful clinical research on outbreak infections. The Mission of ISARIC is to overcome these difficulties and deliver the clinical research evidence that can prevent illness and deaths from outbreak-prone infectious diseases.

Our vision: A global federation of clinical research networks, providing a proficient, coordinated, and agile research response to outbreak-prone infectious diseases.

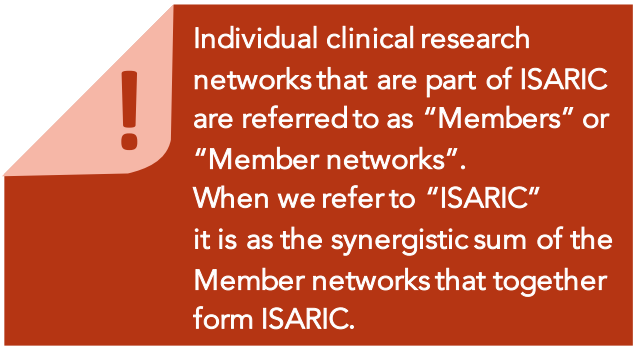
If we are to make progress in delivering the clinical research evidence to reduce the burden of epidemic infections, a collaborative and coordinated approach, that pools global expertise, experience, resources, and patients, is essential. ISARIC's vision is to be the federation of clinical research networks that is global and trusted by the clinical research community and its stakeholders.

ISARIC aims to connect autonomously operating networks and their activities to ensure that, when and where needed, we operate as a coordinated, coherent whole, unlocking, leveraging and disseminating the available knowledge, information, expertise and experience of all networks. ISARIC aims to empower locally-led research, not to integrate or merge all clinical research networks into a single global clinical research network.

Clinical research networks include any formal or informal grouping of clinical researchers of varying size, composition, experience, geographic scope and thematic focus within the field of clinical research on infectious disease outbreaks. They come in different structures and sizes but have the following characteristics in common:

- They are led by clinical scientists;
- They are active in clinical research in infectious diseases;
- They consist of – or have direct access to - two or more clinical research sites (i.e. sites at which potential research participants are located;
- They share the purpose and mission of ISARIC;

Members vary from regional networks, to national networks to international networks and vary in scope and focus (e.g. focused on arthropod-borne virus infections or filoviruses, or covering the full breadth of emerging infections) and harbour different specialities and disciplines.



Clinical research encompasses all research in a clinical care setting that involves the collection and/or analysis of patient data, including biological samples, with the aim of developing new or improved evidence or technology in support of new or improved patient-level or population-level interventions.

Our mission and vision focus on the clinical research response to outbreak-prone infectious diseases. Clinical research in preparation for potential outbreaks, sometimes called 'inter-epidemic research', is as important as research in response to an outbreak.

Figure 2 highlights the complementarities of clinical research preparedness and clinical research response. Whilst ISARIC's ambitions focus on the clinical research response to infectious diseases outbreaks, they encompass both clinical research that is carried out as part of preparing for outbreaks – clinical research preparedness or "inter-epidemic" clinical research – as well as clinical research carried out as part of the response to a specific outbreak – clinical research response.

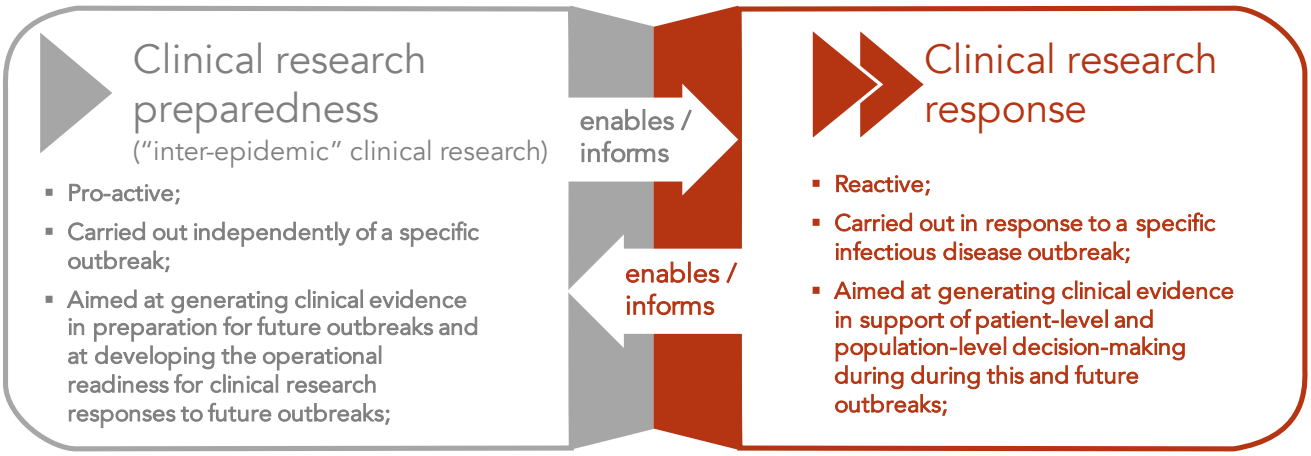


Figure 2: Clinical research preparedness versus clinical research response

2.2 Values

Our values are a shared set of beliefs that are fundamental to what we do and how we should work together and interact.

Collaborate globally

Effective clinical research on outbreak-prone infectious diseases is a global public health good and demands global collaboration; pooling patients, data, samples, technologies, resources,

knowledge and experience. It requires standardisation or harmonisation of research methodologies and tools, and the promotion of interoperability as essential instruments in linking local efforts to the global knowledge and resource base.

Act locally

Clinical research on outbreak-prone infectious diseases should be driven by those with an understanding of the patients and populations at risk. Clinical research responses should build on an adequate local clinical research infrastructure (experience, knowledge, skills, resources) that is operationally ready to rapidly initiate a clinical research response, whenever needed. Local actors should be able to call on international peer support when needed.

Uphold collegiality

We build trust by acknowledging each other's contributions and by building our decisions on open and fair discussion. We have open dialogue, accepting the collective interest of global health and respecting the autonomy of the clinical research networks and the individual colleagues in the networks. In the absence of formal arrangements, we work in good faith. We treat each other equally and build clinical research preparedness and response capacity equitably.

Maintain agility

We are capable of rapidly adapting our activities to the changing contexts of outbreaks. We are flexible in our thinking and in our actions and are prepared to think and act outside of the traditional way of doing things, whenever and wherever required.

3. THE EXTERNAL AND INTERNAL PERSPECTIVES OF ISARIC

In the ISARIC organisational strategy we make a distinction between the external perspective and internal perspective of ISARIC as depicted in fig. 3. Imagine ISARIC as a cube with each of its six sides depicting a specific complementary function of ISARIC: from the external perspective, depicted on the left, we focus on the external mission-oriented goals and services of ISARIC. From the internal perspective, we focus on the internal vision-oriented goals and services of ISARIC.

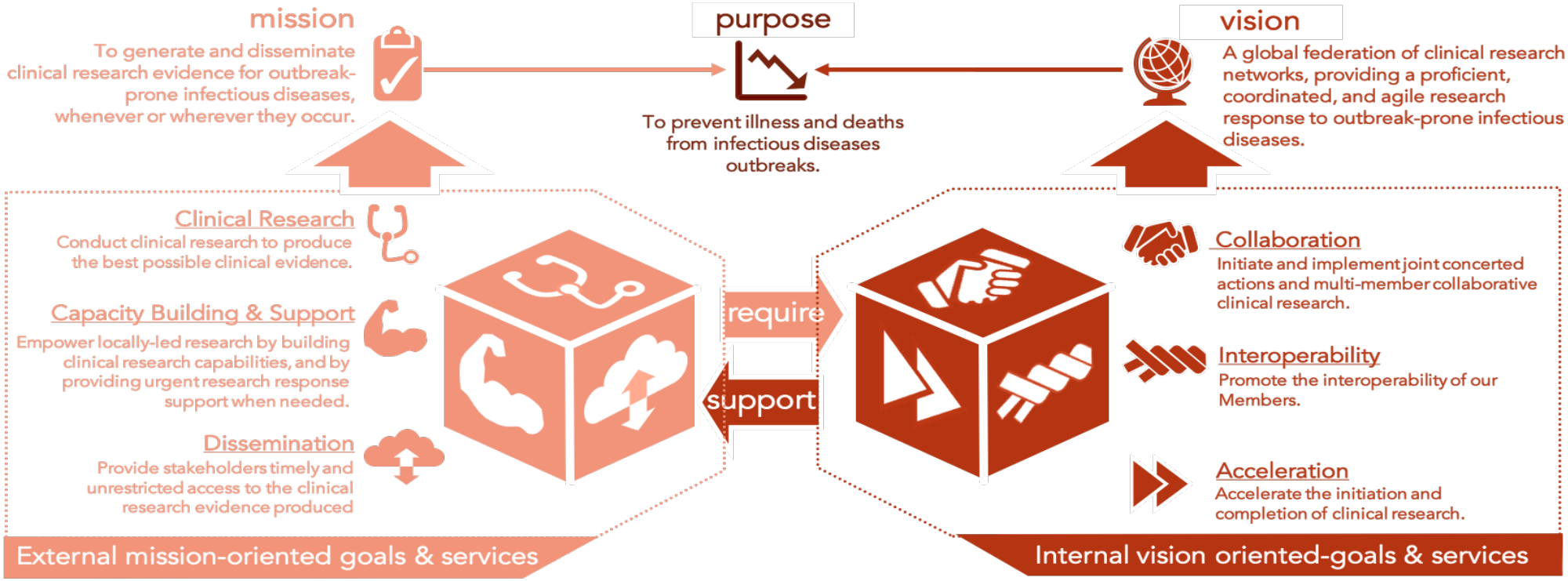


Figure 3: The external and internal perspective of ISARIC

This distinction between the external and internal perspective emphasises that ISARIC is not a single global clinical research network, but rather is a global federation of autonomously operating clinical networks with a common purpose.

The external perspective of ISARIC focuses on the mission-oriented goals and services of our autonomous Members, addressing the question "*how are we going to realize our mission*?" It looks at ISARIC from the perspective of its external stakeholders. These include the patients and populations at risk of infectious diseases outbreaks, healthcare providers and health emergency responders, government public health authorities and regulators, private and public sector funders and/or commissioners of clinical research, the international research community, and the media. For a more detailed description of the external stakeholders of ISARIC see Annex 2.

The internal perspective of ISARIC focuses on the vision-oriented goals and services in ISARIC aimed at developing and delivering added value by ISARIC to our Members, creating the right conditions for them to deliver the mission-oriented goals and services.

These two perspectives on ISARIC are complementary, just like the mission and vision of ISARIC are complementary. When referring to ISARICs goals and services we need to keep both the external and internal perspectives in mind. In the remainder of this document, when relevant this distinction between Internal and External is used to clarify this dual perspective of ISARIC.

4. EXTERNAL GOALS AND SERVICES

ISARIC has three complementary external goals and associated services, which collectively are geared towards realising the mission of ISARIC to generate and disseminate clinical research evidence for outbreak-prone infectious diseases, whenever and wherever they occur.

Figure 4: ISARIC's external, mission-oriented goals and services

4.1 Clinical Research

The central external goal of ISARIC is to generate clinical evidence in both inter-epidemic research as well as during a clinical research response, through clinical research delivered by ISARIC Members (supported by ISARIC's central structures depending on the capacities of Members and the nature of the outbreak).

The two main types of clinical research that ISARIC designs and executes are:

1. Clinical observational studies to:
   - Improve understanding of clinical presentations, disease severity, natural history and outcomes of illness, duration and nature of infectiousness, risk factors for infection and disease, and current standards of care;
   - Provide a better understanding of disease pathogenesis and of the determinants of clinical outcomes;
   - Generate biological resources for characterising the pathogen and components of the immunological response, and for identifying potential diagnostic and prognostic bio-markers.
2. Phase II-III clinical trials to:
   - Evaluate existing or new diagnostics and therapeutics.

As such, ISARIC provides a portal for study sponsors to identify and access clinical trial sites for the evaluation of interventions and for key stakeholders, such as CEPI, EDCARN and the WHO R&D Blueprint to commission clinical studies to inform their work.

Clinical Research in ISARIC spans from design to evaluation and reporting of clinical research:

- Design: this involves the design of the research and development of all aspects of the study protocols describing the purpose and objectives of the study, key design elements (randomised trials and observational studies), primary and secondary outcome measures, patient inclusion and exclusion criteria, site selection criteria, statistical and data management plan, sample size, etc.
- Execution: this involves the execution of clinical research studies, including (overseeing) patient inclusion and sampling, data collection, site monitoring, quality assurance, safety monitoring, reporting of results etc.
- Evaluation and reporting: to continuously improve performance, clinical research studies are evaluated on efficacy (did they generate the clinical evidence needed) and efficiency (were the results obtained in time and on budget). The results of the evaluations feed back into the design of new and/or other studies.

Commissioning of work

A specific role ISARIC can fulfil is to function as an expert commissioner of work for funding agencies. Rather than funding individual clinical research projects or networks, external funding agencies can call upon ISARIC to act as the intermediary between the funding agency and our Members, with the aim of accelerating the implementation of critical clinical research. For funding agencies, this offers the advantages of only having to interact and deal with ISARIC instead of a range of individual researchers and of being able to leverage the resources of ISARIC to commission and initiate clinical research.

4.2 Capacity Building & Support

Realisation of ISARIC's mission requires having an adequate infrastructure and capabilities in place to produce clinical evidence, whenever and wherever needed. Services in support of this goal include activities ranging from ad-hoc mentoring of individual researchers to the design and implementation of long-term capacity development programmes, including at regional levels. The common aim is to transfer experience, knowledge, skills and resources within ISARIC to those who need it, in support of building a worldwide clinical research and preparedness capacity. Activities can include:

- Individual mentoring of (clinical) researchers and peer-review of research by Members;
- On-site practical training workshops, as part of clinical site training;
- Practical training courses on the conduct of clinical research during outbreaks;
- Open on-line educational resources;
- Expert workshops/presentations (physical or remote) to selected groups;
- Providing organisational and managerial support and resources, to improve preparedness for outbreak clinical research.

In some circumstances, locally-led research during health emergencies will be impeded by a mismatch between the available resources, capabilities or experience and the scale or nature of the health emergency and the required research response. When needed and requested, ISARIC will provide technical and operational research support to local investigators.

4.3 Communication and Dissemination

The third external goal of ISARIC is to make available the clinical evidence generated and expert opinions, experience and tools collated by ISARIC to those who need it, whenever they need it.

The clinical evidence generated in ISARIC forms the main content communicated by ISARIC, in different shapes and sizes to the different target audiences. Next to the clinical evidence generated, other sources of content include more 'generic' expert experience, knowledge and tools available within ISARIC, that can form valuable input to, for instance, the clinical research community or public health authorities. A particular aspect of communication includes advocacy, aimed at putting the purpose, mission and vision of ISARIC higher on the political, economic and societal agenda at national and international level.

The key target audiences of ISARIC's activities are the external stakeholders as described in Annex 2: the patients and populations at risk of infectious diseases outbreaks, healthcare providers and health emergency responders, government public health authorities and regulators, private and public sector funders and/or commissioners of clinical research, the international research community, and the media. The overriding goal of all communication and dissemination activities is to ensure that the impact of ISARIC's activities on its mission is maximised by communicating the activities and results in a timely and unrestricted fashion. ISARIC provides access to the

evidence it generates under FAIR principles (Findable, Accessible, Interoperable and Reusable) in a timely fashion, in pursuit of maximizing the impact on patient-level treatment and population level prevention and control measures.

5. INTERNAL GOALS AND SERVICES

This section considers the internal perspective of ISARIC, focusing on the vision-oriented goals and services in ISARIC.

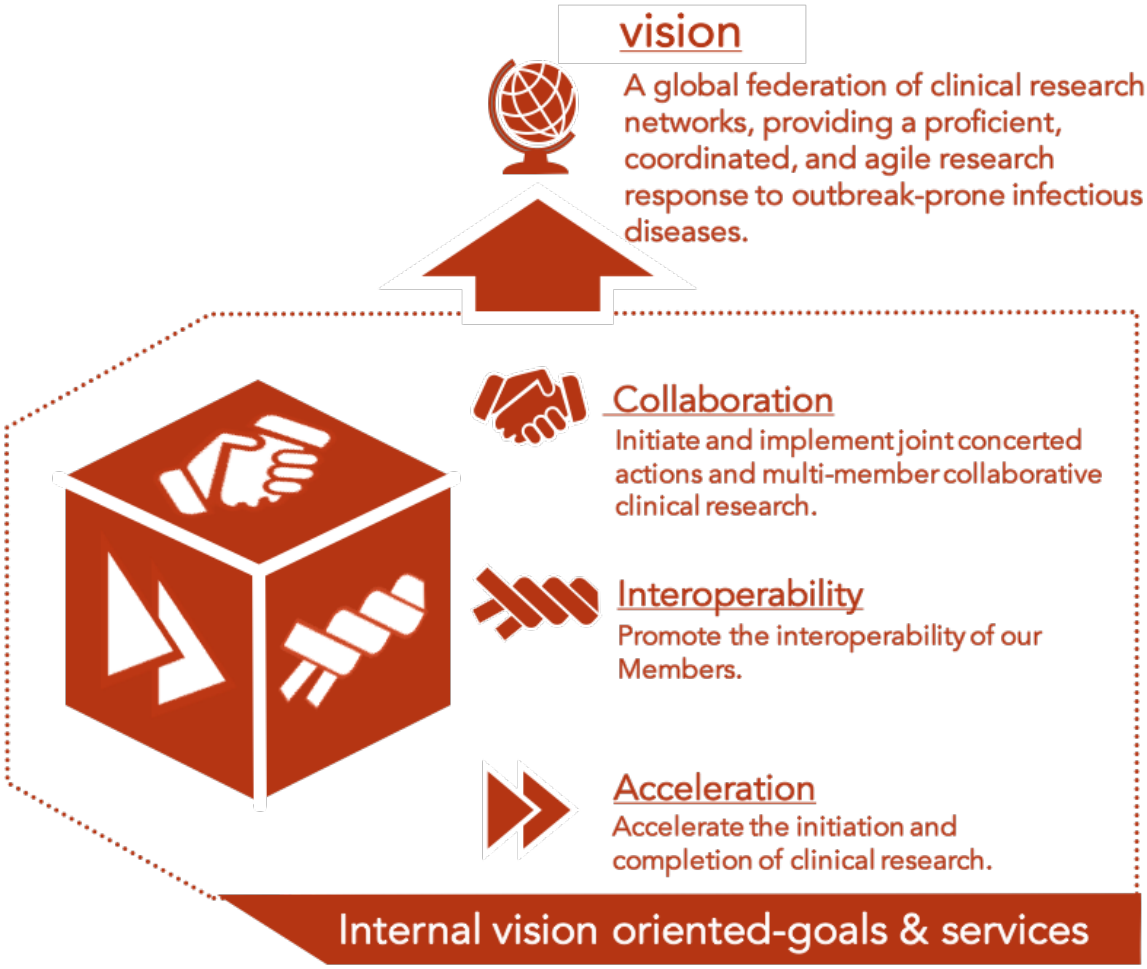


Figure 5: ISARIC's internal, vision-oriented goals and services

5.1 Internal Goals

In support of its vision, ISARIC has three internal goals: **Collaboration, Interoperability, and Acceleration.** Individually and collectively, the realisation of these internal goals will contribute to ISARIC empowering its Members to operate as the global federation of clinical research networks, providing a proficient, coordinated and agile research response to outbreaks.

5.1.1 Collaboration

For ISARIC to be a truly global federation it needs to be inclusive and bring clinical research networks with complementary infrastructures and geographic coverage on board as Members. Building and maintaining an up to date membership is therefore a crucial and first condition for ISARIC to realise its vision of a global federation of clinical research networks.

The primary goal of ISARIC is to promote and facilitate collaboration between Members by initiating and implementing joint collaborative multi-Member Projects that transcend the geographic and disciplinary boundaries of our Members. The term "Project" is used here in the broadest sense. Projects initiated and implemented by ISARIC can involve:

- large-scale international observational studies as part of clinical research preparedness, such as SPRINT-SARI (see https://isaric.tghn.org/sprint-sari/) making use of the interoperability of the participating Members;
- large scale international RCTs, that can be adapted quickly to evaluate the most appropriate interventions during an outbreak;
- smaller more targeted projects involving only one or two Members, focussed on specific scientific questions or problems (such as our work on MERS-CoV and avian influenza), or as part of training and capacity building efforts;
- the rapid set up of clinical research studies as part of the international response to (emerging) outbreaks such as was done for the recent Ebola outbreak in west Africa;
- time-limited technical tasks, such as the preparation and agreement of data standards, and the development of research tools.

5.1.2 Interoperability

Effective cross–Member collaboration in clinical research preparedness and response demands globally unlocking, mobilizing and connecting the experience, knowledge, data and information and resources of our Members.

In the context of clinical research preparedness and response, developing Member interoperability is expected to greatly enhance the efficiency of external services of the Members. The result is a strong and coherent globally connected clinical research effort through interoperability at three levels: technical interoperability, process interoperability and organisational interoperability, as depicted in figure 6:

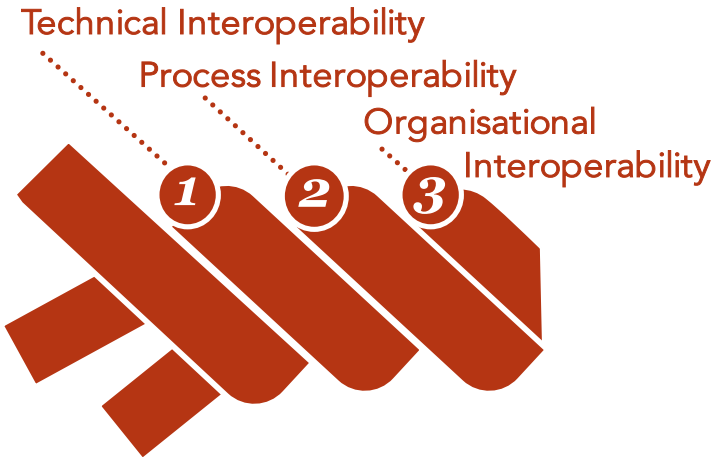


Figure 6: The three levels in realising member interoperability

- Technical Interoperability: refers to the extent to which by the Members can exchange data, information, services and other outputs and the networks can act upon this information, services and outputs. This includes for example developing and implementing standardized data formats, case definitions, variable names and protocols.
- Process Interoperability: refers to the extent to which the Members align their activities, policies and procedures to facilitate a joint output. This involves for example using common or consistent data sharing or bio-banking policies.
- Organisational Interoperability: refers to the extent to which the member networks use their technical and process interoperability to effectively operate together and function as a coherent global clinical research preparedness and response effort. This involves for example consistent outbreak response plans and communication structures.

5.1.3 Acceleration

Time is of the essence in clinical research on epidemic-prone infectious diseases. Time and again, local clinical researchers faced with an outbreak cry out for immediate financial and technical support to help them gather the evidence that everyone needs: time and again that support comes too late. The third internal goal of ISARIC is to accelerate the initiation and completion of clinical research by our Members (and others). Due to its complexity and various administrative and organisational bottlenecks, clinical research typically starts too late, and takes too long to reach the required numbers of patients, to generate the timely clinical evidence needed to improve clinical and public health responses to an outbreak. Reducing the time needed to start and complete the (right) clinical research study(ies) can save lives. ISARIC is therefore committed to developing and testing innovative approaches to accelerating clinical research.

5.2 Internal services

Our Internal Services encompass the activities performed ***in*** ISARIC in pursuit of realizing our Internal Goals – Collaboration, Interoperability and Acceleration. They constitute ISARIC's mechanisms that are made available to our Members for supporting the external services of our Members. These services are delivered by the ISARIC central support structures (i.e. the Global Support Centre, see section on Governance) to our Member clinical research networks and consist of six complementary services as depicted in fig. 7.

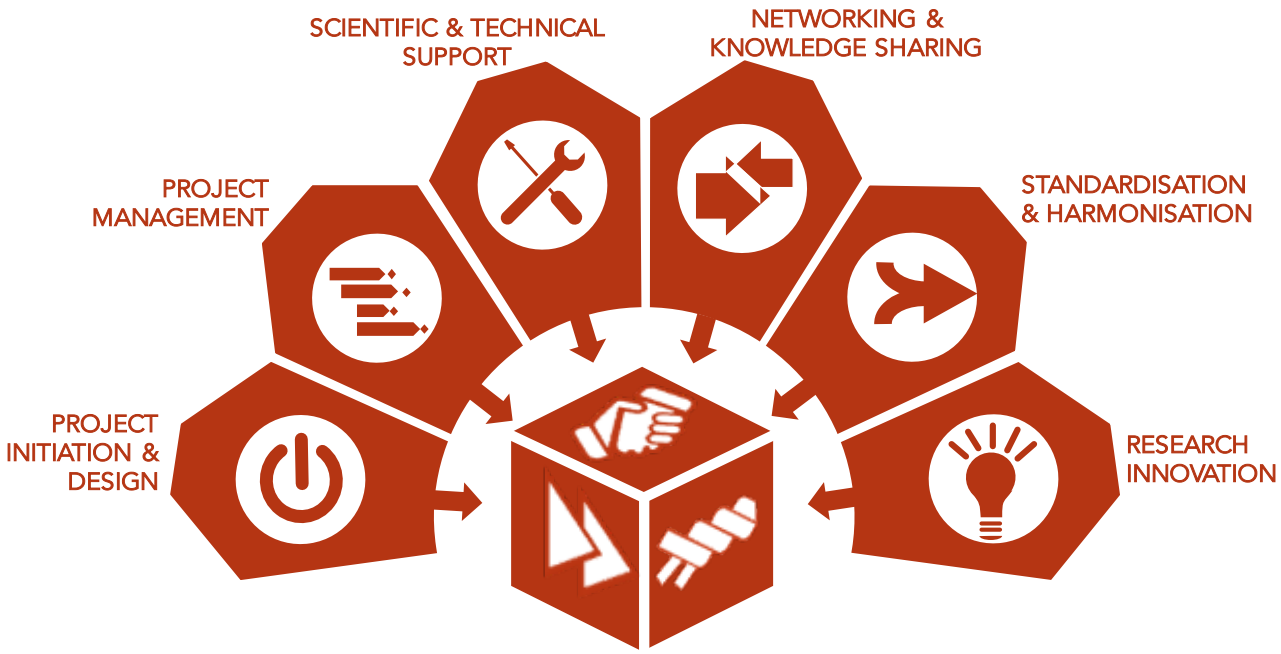


Figure 7: ISARIC's internal service offering in support of its strategic goals collaboration, interoperability and acceleration

5.2.1 Project Initiation & Design

Our project support services are geared primarily towards our internal goal 1. Collaboration. They encompass ISARIC's function as the birthplace, incubator and caretaker of investigator-led collaborative research projects by providing a suite of project management and technical support services to our Members. ISARIC can fulfil a catalysing or accelerating role in bringing together its Members and other parties to develop collaborative research projects. This can range from initiating and designing:

- Targeted clinical research projects involving (some) Members, such as observational studies and Phase II or III clinical trials as part of outbreak preparedness and response efforts;
- Large scale multi-annual, multi-member projects, such as perpetual inter-epidemic platform studies like SPRINT-SARI;

- To the design and facilitation of new regional (Member) networks, such as the initiating role of ISARIC in the establishment of PREPARE (see www.prepare-europe.eu), and more recently ALERRT (African coaLition for Epidemic Research, Response and Training).

ISARIC as a not-for-profit initiative relies primarily on public funding sources for building and sustaining its research support infrastructure and implementing its activities. This applies to the individual Members as well as for the ISARIC central governance infrastructures and processes. Identifying, applying for and realising sufficient income is therefore of crucial importance to the sustainability of ISARIC. ISARIC can support its Members through all phases of funding acquisition.

5.2.2 Project Management

The execution phase of ISARIC projects involves non-scientific project management activities such as progress monitoring and reporting, contract management, and communications. The ISARIC Global Support Centre can provide its Members with financial, legal and contractual support and advice when needed.

5.2.3 Scientific and Technical support

The execution of the scientific and technical activities of ISARIC projects is typically done by our Members. However, in cases where the local Member(s) concerned do not yet have an adequate research infrastructure, or in complex emergencies, ISARIC can mobilize the required infrastructure from other Members or from the Global Support Centre to support implementation by local investigators.

5.2.4 Networking & Knowledge Sharing

Our Networking and Knowledge sharing services are aimed primarily at building Interoperability. They promote connecting the infrastructure and activities of the Members, (internal connections) as well as connecting the Members to global activities and vice versa (external connections). The activities under this service set encompass the following:

- Membership development: Outbreaks are not confined to any region of the world, so ISARIC needs to be global. In the current membership of ISARIC the regions of the world that are most vulnerable to outbreaks are relatively underrepresented. Moreover, Members themselves evolve in terms of their composition and activities. Membership development therefore involves:
  - Periodic mapping of the ISARIC membership (composition, infrastructure and activities);
  - Identifying potential clinical networks in underrepresented Regions, focusing on Low and Middle Income Countries (LMICs) and infectious disease outbreak 'hotspots' and supporting their development into regional clinical networks as Members of ISARIC;
  - Development and maintenance of the ISARIC Membership Agreement;

- Communication and networking: Within the Membership there is a clear need for more frequent direct interactions between Members, preferably by means of face-to-face meetings, or, if not feasible, by means of web conferencing. ISARIC will strive to organize and facilitate periodic Member meetings (physical and virtual) around topics of specific interest.

  ISARIC has played an active role in facilitating interactions between clinical scientists on behalf of key global health stakeholders such as WHO, with ISARIC convening and hosting large scale teleconferences during the Ebola and Zika Public Health Emergencies. ISARIC will continue to fulfil this networking role.

- ISARIC representation: ISARIC harbours some of the world's leading experts on clinical research in infectious diseases. ISARIC can channel this collective knowledge and expertise to international advisory committees and working groups. This way ISARIC's collective knowledge and expertise is unlocked to these fora, in support of specific actions that align with ISARIC's mission. For the Members, this provides a 'voice' in international discussions and policymaking regarding the design of international clinical research preparedness and response activities. For the international health authorities and policy makers this provides single and efficient access to a global operational arm of relevant local clinical research infrastructures.

- ISARIC branding and communication: This involves establishing and protecting ISARIC's name and reputation as the global federation of connected clinical research networks, whilst at the same time protecting the interests and brand of Member networks.

- Knowledge and data sharing: ISARIC provides Members with access to web-based knowledge sharing platforms and programmes, including newsletters, online repositories for research tools and knowledge, discussion fora. This enables Members to access quickly the relevant information, data and knowledge within the ISARIC community, in support of their external services.

5.2.5 Standardisation and Harmonisation

Standardisation and harmonisation are key aspects in building Member interoperability. ISARIC develops and promotes, on behalf of its Members and the global clinical research community, harmonised and standardised:

- Tools, methodologies, and systems: e.g. research protocols, data definitions and management systems, trial designs to realise technical interoperability across the members in support of efficient and fast data and information exchange.
- Processes: e.g. compatible data sharing and bio-banking policies.
- Governance: this involves linking the governance and management structures of Members in support of organisational interoperability. This is described further in the section on Governance.

5.2.6 Innovating research methods and processes

This set of internal services of ISARIC are geared primarily towards Acceleration of clinical research. They involve addressing the need for innovating, testing and introducing novel research methodologies and coming up with ways to speed up the process of clinical research by addressing factors that delay the process of starting and conducting clinical research.

The challenges of patient-based clinical outbreak research cannot be adequately met by current models of conducting clinical research. These usually require long lead times, predictable epidemiology, predictable funding, and fixed research assets. Recent innovations in clinical trial designs, such as platform clinical trials, may offer advantages for clinical research preparedness and response to outbreaks. ISARIC will develop, test and validate innovative approaches and methodologies.

5.3 ISARIC Projects and Programmes

The implementation of ISARIC's strategy is done through the design and implementation of ISARIC Projects, involving internal services in support of clinical research by our Members. An ISARIC Project is:

- A coherent set of external services by ISARIC Member(s), supported/facilitated by a coherent set of internal services of ISARIC;
- with a defined set of objectives, deliverables, timeline and budget;
- executed by a Project Team consisting of ISARIC GSC staff and – if relevant – staff of our Members and
- carrying the ISARIC brand.

ISARIC Projects can be of different scale in terms of budgets, members involved and timelines. They can involve different combinations of internal services. In figure 8, three examples of typical ISARIC Projects are shown. Other combinations of internal services are also possible.

Figure 8: Examples of ISARIC projects

a. This ISARIC Project combines the following activities: **Project Initiation & scientific and technical support:** ISARIC organises (a series of) Member meetings, where (a group of) our Members come together to exchange ideas and experiences and jointly define and design a new collaborative research project, for which ISARIC also seeks to acquire project funding. The desired end-deliverable of the Project is an application for funding, describing the proposed ISARIC collaborative research Project.

b. This ISARIC Project combines the following activities: **Project Management; Technical & Scientific Support and Standardisation & Harmonisation:** This ISARIC Project could be the successor of example Project (a), where the funding application was awarded and ISARIC provides project management and technical support in the execution stage (and develops and implements standardised clinical research protocols).

c. This ISARIC Project combines the following activities: **Networking and Knowledge sharing and Innovation Research.** This ISARIC Project involves the set-up of an ad-hoc ISARIC Expert Group, consisting of selected representatives of our Members, that exchange their expertise, knowledge and experience in a joint research project developing and testing novel clinical research methods and processes.

ISARIC Programmes

To ensure the long-term alignment and consistency of ISARIC Projects with the ISARIC Goals and Mission, ISARIC Projects can be clustered into **ISARIC Programmes.** An ISARIC Programme is a coherent set of ISARIC Projects, designed around strategically important themes that together contribute to the ISARIC external and internal goals. An example of an ISARIC programme could be an ISARIC avian influenza Programme, consisting of several connected ISARIC Projects addressing avian influenza outbreaks.

6. GOVERNANCE

6.1 Design principles

This section describes the governance structure of ISARIC. The challenge for ISARIC's governance structure is to find a balance between, on the one hand, ISARIC Members being autonomous, with their own identities, priorities and responsibilities, and on the other hand, the connecting and facilitating services of ISARIC requiring formal and centrally led mechanisms, that support ISARIC's vision of being a federation of networks delivering coordinated clinical research.

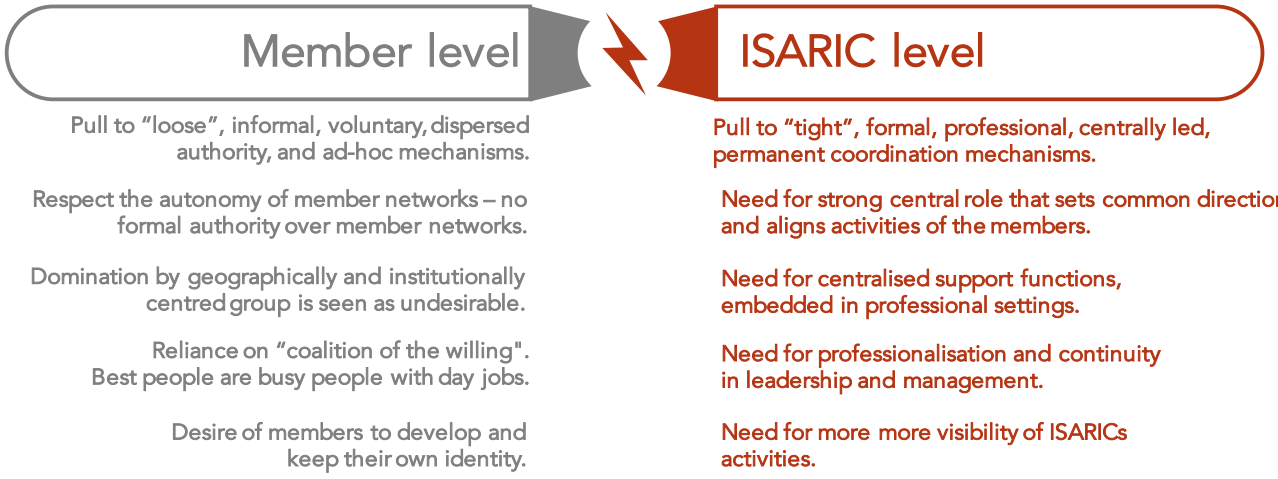


Figure 9: Tensions in the ISARIC governance structure

ISARIC's governance structure should accommodate both forces, and reflect its values. This has led to the formulation of design principles that underpin ISARIC's governance structure:

- Member autonomy: the structure and processes will respect the autonomy of the Members to operate independent of ISARIC if so desired;
- Member leadership and ownership: the structure and processes will promote local (member-level) leadership and ownership of activities and results;
- Member participation: the structure will balance authority and responsibilities across Regions, disciplines and gender and will promote active participation of all its Members in ISARIC decision-making and activities, enhancing member commitment to ISARIC's mission and vision;
- Agility and responsiveness: the structure and processes will support quick and agile clinical research responses to outbreaks whenever and wherever needed;

- License to operate: the structure and processes will enable the efficient implementation of the internal services and provides the ISARIC governance bodies with a clear mandate from our Members and external stakeholders;

In the following sections, we have described:

- The federation structure, describing the relationship between ISARIC and its Members;
- The organisation structure, describing the roles and responsibilities of the ISARIC organisational bodies and management processes;
- The legal structure of ISARIC;

6.2 Federation structure

In the current federation structure (see fig 10a.) ISARIC distinguishes three types of members: network membership, individual membership, and observers. Members include networks of organisations, individual organisations as well as individuals.

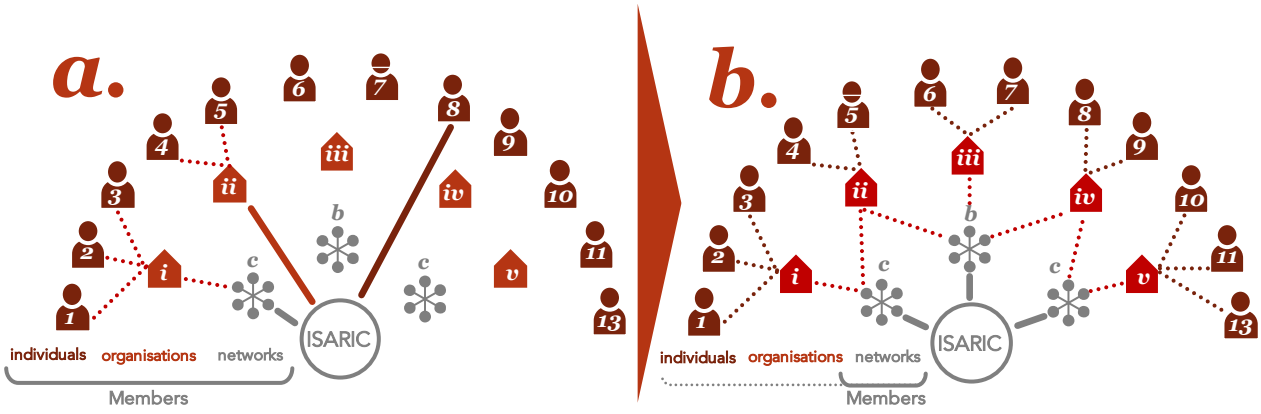


Figure 10: Current federation structure (a) versus the envisaged federation structure (b)

The current membership structure of ISARIC (fig. 10a), in which the members are a combination of networks of organisations, organisations and individuals, has shortcomings. First, it makes the governance of ISARIC complex (e.g. differences in rights and obligations between individual Members, Organisation members and Network Members). Second, with different types of Membership there is a risk of overlaps, with individuals and organisations being linked to ISARIC in multiple, potentially conflicting, ways. Third, allowing individual organisations and individuals as Members essentially goes against the values of ISARIC, where collaboration and connections across organisations are central to its vision and mission.

In the desired federation structure (fig. 10b.) only *networks* can be Members of ISARIC. This way the internal functions of ISARIC can be implemented efficiently, building on the infrastructures and capabilities in the Member networks. In moving towards "network-only" Memberships, ISARIC will:

- promote the establishment of regional and/or thematic networks of organisations;
- Support the sustainability of these Member networks;
- Encourage organisations and/or individuals that are not (yet) part of a network, but who do have relevancy to ISARIC's mission and vision, to join (or form new) ISARIC Member networks.

6.3 Organisation structure

Here we describe the desired governance structure and management processes of ISARIC. This structure is designed for growth, depending on the availability of sufficient funding and suitable candidates for the management positions and support staff.

Figure 11. shows the desired organisation structure of ISARIC consisting of the Member Assembly, the Board of Directors, the Executive Director, the Global Support Centre, Project Teams and the Advisory Board.

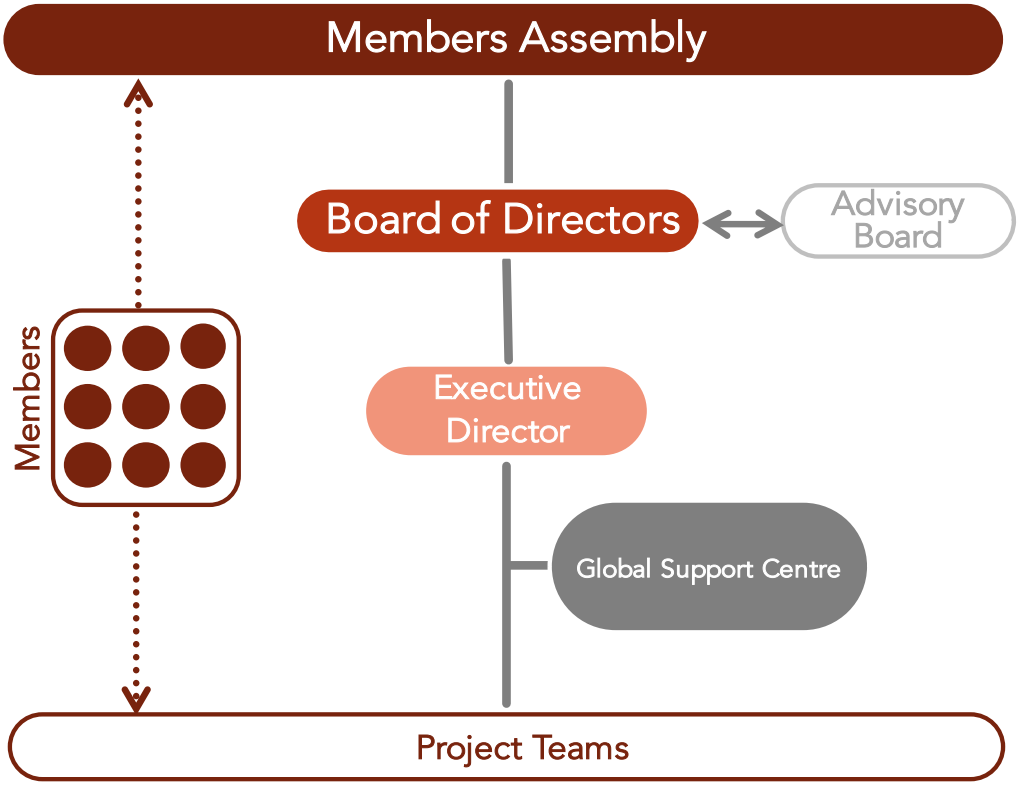


Figure 11: ISARIC organisation structure

6.3.1 Member Assembly (MA)

The MA includes the representatives of all Members. A Member is a clinical research network that:

- is founded, led and run by academic investigators (i.e. not led by industry);
- is active, with scholarly contributions that are attributable to the network and in research areas relevant to ISARICs mission and purpose;
- is multicentre, involving more than one location, department, hospital, agency etc.;
- has access to patients for enrolment into studies of relevance to ISARICs mission and purpose;
- has signed the ISARIC Member Agreement.

Each Member has one vote in the MA. The MA has the following responsibilities:

- It elects, suspends and dismisses the Board of Directors and oversees its functioning;
- It sets the ISARIC five-year Strategy Plan;
- It decides on changes in the ISARIC Governance structure;

6.3.2 Board of Directors (Board)

The coordination and management of ISARIC is delegated by the MA to the Board of Directors (hereafter: The Board). The Board has the following responsibilities in ISARIC:

- It decides on the accession, suspension or discharge of Members;
- It appoints and oversees the functioning of the Executive Director.
- It implements the ISARIC Strategy, monitors the progress towards the Internal Goals of ISARIC and reports to the Member Assembly;
- It decides on the selection of the GSC Host Institution;
- It sets and decides on changes to the ISARIC Annual Plan and on the initiation of new and major changes to ISARIC Projects;

The Board consists of twelve persons, elected by the Member Assembly, comprising one Chair, four vice-Chairs and seven Board members. ISARIC strives for a balanced division of the twelve seats in the Board over the nine Regions, accommodating the need for more regionally balanced leadership of ISARIC. The Chair of the Board is the primary figurehead of ISARIC, acting as the highest representative of ISARIC towards our external stakeholders. Persons cannot serve on the Board and be the representative of a Member in the MA at the same time.

6.3.3 Executive Director (ED)

The coordination of ISARICs internal services is delegated by the Board to an Executive Director (ED) who is responsible for:

- Implementing the Annual ISARIC Plan and coordinating the internal services of ISARIC to our Members;
- Monitoring the progress of the activities in the ISARIC Projects and reporting to the Board.
- Running the day-to-day management of the Global Support Centre (GSC);

The ED is the first point of contact of the ISARIC GSC for all Members and represents ISARIC together with the ISARIC Chair in external communications and meetings when relevant.

6.3.4 Global Support Centre (GSC)

The Executive Director position is supported by a Global Support Centre (GSC). The GSC provides technical and administrative support needed to deliver the internal services of ISARIC to its Members.

Function	Role
Technical officers	Providing scientific and technical support to ISARIC Projects, such as clinical trials management, data management, and bio-statistics.
Legal and Contract officer(s)	Assisting in legal and contractual matters (e.g. NDAs. MTAs, IP, employment contracts).
Finance & Admin officer(s)	Financial and project administration.
Communications and Public Relations officer(s)	Implementing the ISARIC internal communications and external communications.

The Global Support Centre (GSC) of ISARIC is embedded in the professional academic environment of a GSC Host Institution, providing it full access to all supporting office systems and infrastructure (e.g. fully equipped offices, PCs/laptops, ICT and telecom services, office software, meeting rooms). The Host Institution will also function as the formal employer of the Executive Director and the GSC staff, in the absence of an ISARIC legal entity (see paragraph 6.4).

The current equivalent of the GSC, the Coordinating Centre of ISARIC, is hosted by the Centre for Tropical Medicine and Global Health at the University of Oxford (UOXF). To accommodate a smooth transition from the current ISARIC structure to the new structure, UOXF will be requested to remain ISARIC's GSC Host Institution for a period of five years after which a new GSC Host Institution is selected via the process as described in Annex 1.

6.3.5 Project Teams (PT)

At the operational level, Project Teams are responsible for the coordination and execution of ISARIC Projects. PTS are staffed by persons from the GSC and our Members and are led by a PT leader, who is responsible for the coordination and management of the PT and reporting the progress of the work to the Executive Director. A PT is dismantled when the ISARIC Project for which it is responsible has finished.

6.3.6 Advisory Board (AB)

The current two external Advisory Boards - the Independent External Advisors and the Stakeholder Advisory Board – are to be combined into one single Advisory Board (the AB). The AB has no decision authority in ISARIC. Its role is to advise the Board on the implementation of the ISARIC Strategy and decisions regarding changes to our strategy and structure. The AB will consist of representatives of the external stakeholders of ISARIC (see Annex 2). AB members will be invited by the Board for a period of two years.

6.3.7 Growth model

The presented ISARIC governance structure can evolve along with the increase of our membership and activities (as measured by the number of ISARIC Projects and the average size of the ISARIC Projects in terms of budgets and participants).

- Member Assembly: The MA can increase in size proportionally to the number of Members of ISARIC. However, the number of ISARIC members is not expected to increase dramatically. The desired expansion of the membership towards underrepresented Regions is expected to be offset by a decrease in members due to the desired transition into 'networks only' membership.
- Board of Directors: The Board of Directors, with twelve seats will not change in size as ISARIC grows in members and Projects, however the time spent by each Board member will increase. At the current size of ISARIC and the level of activities we estimate that Board positions will be part-time voluntary positions (approx. 0.1 FTE for Board members, 0.2 FTE for the Chair), increasing by about 0.1 FTE per position with the increase of ISARIC activities.
- Executive Director: At the current size of ISARIC and the level of activities, we estimate that the Executive Director is a 1 FTE position. As ISARIC activities increase, other officers can be added to assist the Executive Director.
- Global Support Centre: At the current size of ISARIC and the level of activities, we estimate that the central staff at the GSC are all 0.8-1 FTE positions. Additional support staff can be added to the GSC provided that additional funding for their salaries is secured. Additionally, regional support centres in different Regions can be established, as support nodes to the GSC, as the need arises and provided funding is available.

6.4 Legal structure

Currently, ISARIC is an informal collaboration between (groups of) academic institutions and individual researchers that operate as a 'coalition of the willing' under a set of shared guidelines and rules. Establishing ISARIC as a legal entity has several potential advantages:

- Independence: By establishing an independent legal entity, ISARIC can develop its independent role as an international federation. The central position of the University of Oxford as ISARIC's host-institution of the Coordinating Centre, and its associated function as the contractual partner for ISARIC's activities, has led to a misperception amongst some Members and other stakeholders that ISARIC is an Oxford-led or even Oxford-dominated initiative. This misperception hampers the realisation of our vision.

- Clarity of focus and accountability: As an independent legal entity, ISARIC can operate with singularity of purpose, being accountable to its Members, and without explicit or implicit obligations and expectations to an academic host institution.

- Contractual relationships: establishing a legal entity will enable ISARIC to enter contractual relationships with its stakeholders, independent from the GSC Host Institution. This includes:
  - Funding: the legal entity can receive funding directly or function as a Coordinator or partner in externally funded (research) projects, which will better enable ISARIC to deliver its Project Support services and commission research;
  - Resource acquisition: the legal entity can take on the role of employer of the GSC staff and buy or lease equipment, and hire external services. This would support building the operational support infrastructure to deliver our internal services.
  - Collaborations: Furthermore, it can act as the autonomous and impartial representative of the membership with international health authorities and organisations and can enter contractual relationships with these stakeholders (e.g. industry-driven trials), which would benefit the delivery of the internal connecting and research services.

- Visibility: ISARIC would no longer be fully dependent upon other legal entities (e.g. University of Oxford), for channelling funding or acting as the contractual partner on behalf of ISARIC. This in turn would benefit ISARIC's visibility in external communications of the collaborative project it participates in or even has initiated;

Incorporating the legal structure into the overall governance structure

If established, the legal entity would formally encompass the Board of Directors (or its equivalent depending on the entity), the Executive Director and the Global Support Centre, as depicted in fig.12.

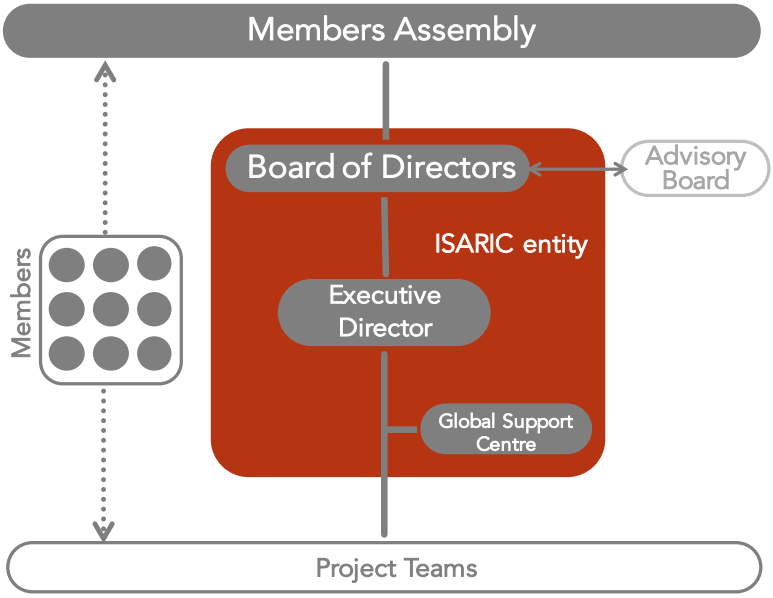


Figure 12: ISARIC legal entity

There are several options for ISARIC to introduce a legal framework (e.g. international association, not-for-profit foundation or other legal entities), including frameworks that would allow ISARIC to be affiliated with and benefit from a host academic institution. The choice of the legal entity (or entities) and the choice of the country of establishment of the entity(ies) directly influences the legal and contractual landscape of ISARIC in terms of:

- Governance: the choice of the legal entity and the country of establishment determines the governance of the federation (who has what authority) and the contractual relationship with our Members (e.g. members in an association, shareholders, external contract partners);
- Finance: income tax, financial regulations;
- Regulations: e.g. employee contracts, employee benefits, pensions; permits; visa requirements; data and privacy laws, ownership of results; insurance;

The impact of these aspects on the ability of ISARIC to function as a global federation and the feasibility of its internal goals will need to be thoroughly investigated to make a well-informed decision on the type of legal entity and the country of establishment.

Organisational Strategy 2018 – 2022

ISARIC

International Severe Acute Respiratory and emerging Infection Consortium

ANNEXES

Annex 1: Operations and Decision making processes

In this Annex, the operational processes and policies and associated decision-making process in ISARIC are described.

Annual Programming cycle

The ISARIC multiannual strategy – our purpose, mission, vision, (internal and external) goals and (internal and external) services – forms the basis for the Annual Plan. The Annual Plan is an annually updated operationalisation of our Strategy that sets the annual agenda for ISARIC and contains concrete targets for the ISARIC Projects and performance indicators, based on which we will monitor the progress towards our internal goals.

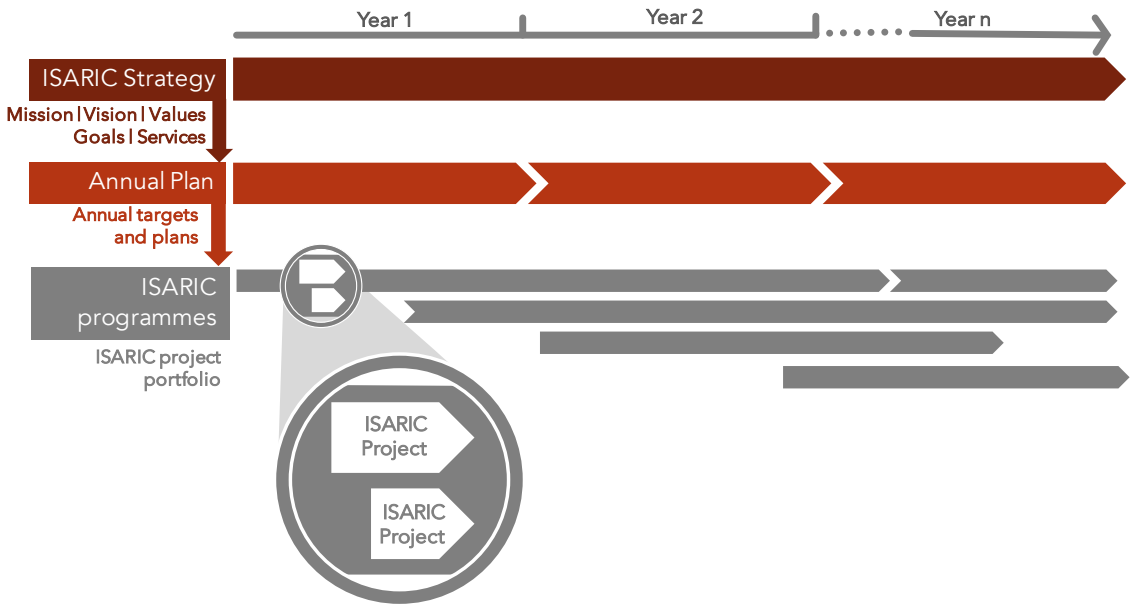


Figure 13: ISARIC Strategy to annual plan, programmes and projects

Goal	Performance Indicator examples
1. Interoperability	• Number of participating organisations in Members • Number of joint meetings organised • Number of shared research tools and methods used by Members; • Number of joint processes initiated by Members
2. Collaboration	• Number of collaborative research projects involving more than one Member; • Average number of members involved in ISARIC Projects • Joint publications presenting results of innovation research
3. Acceleration	• Average # days to receiving ethical approval for ISARIC studies • Average # days to enrolling first patient in ISARIC studies • Average # days to reaching target inclusion
Cross-Goal	• Number of Members • Amount of funding acquired/ New staff hired

We will implement an annual programming cycle as depicted in fig. 14. Month 1 can be any time of year (e.g. the annual cycle runs from May to April).

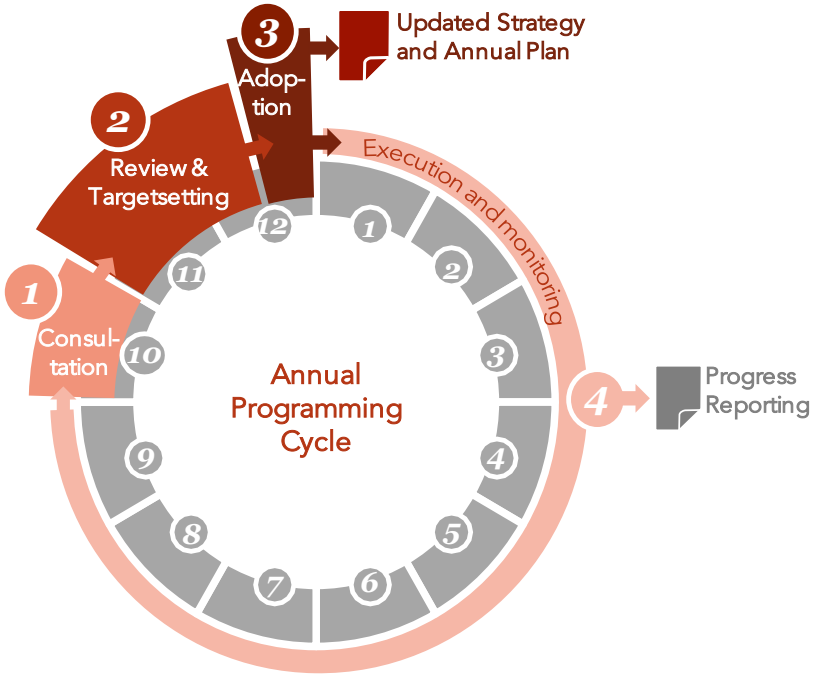


Figure 14: ISARIC's annual programming cycle

The implementation of the annual programming cycle falls under the responsibility of the Board and involves four steps:

- Consultation: The cycle starts with a round of consultations of the Members and Advisory Board (AB). Based on the progress reporting the Members and AB are asked to review the ISARIC Strategy and provide their inputs for the annual targets and for the initiation/adaptation of (new) ISARIC Projects and/or Programmes in pursuit of these targets.

- Review and Target-setting: based on the inputs received in the round of consultation the ISARIC Strategy is updated and the Annual Plan is developed, with new targets for the internal goals and concrete suggestions for new or updated ISARIC Projects and Programmes.

- Adoption: the third step is the formal adoption of the updated ISARIC Strategy (by the MA) and the Annual Plan (by the Board), according to the processes described in Annex x.

- Execution and monitoring: the fourth step is the execution and progress reporting of the ISARIC Programmes and Projects by the Project Teams.

Internal meeting and reporting cycle

Figure 15 depicts the formal planned management meetings in ISARIC. The months should be in sync with the annual programming cycle of figure 14.

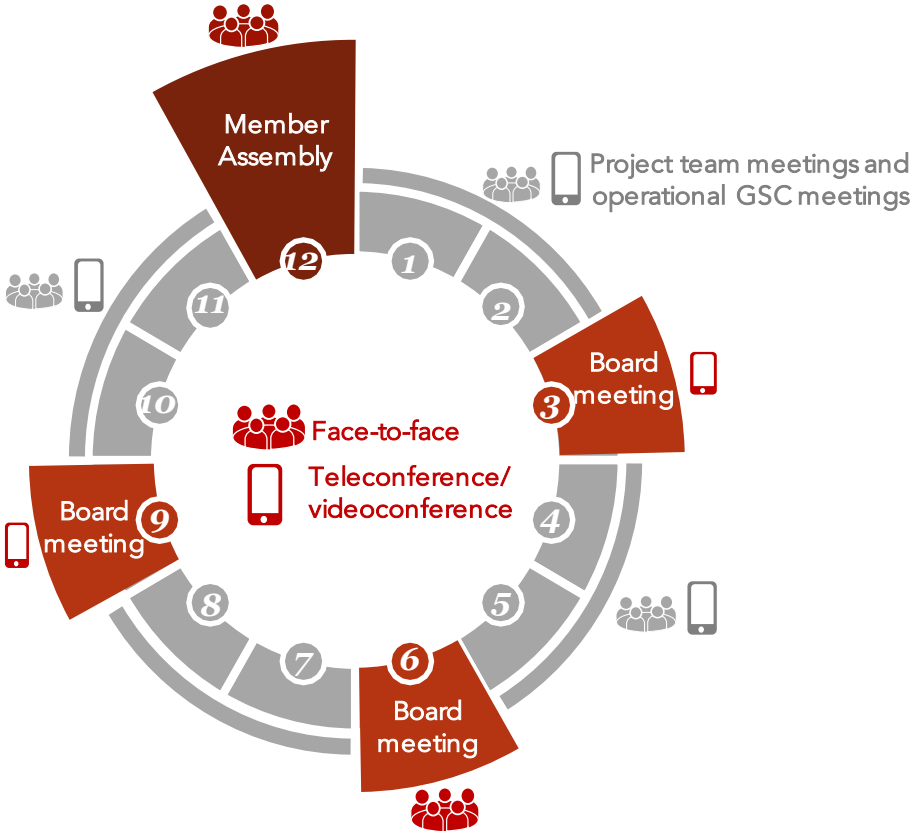


Figure 15: Annual meeting cycle

The table below lists details about each of these planned meetings. The implementation of the Annual Member Assembly meeting and face-to-face Board meeting is contingent upon acquiring sufficient funding.

All meetings are organised with the support of the GSC. Meeting agendas and supporting documentation are circulated prior to the meeting, including any issues that need formal decision-making.

ISARIC management meetings

Governance Body	Meeting
Project Teams	Frequency and type of progress meetings are at the discretion of the Project Team.
GSC	• Monthly management meetings; • Purpose is to discuss operational affairs and status of running ISARIC Projects; • Chaired by the Executive Director; • Board members can dial in via teleconference if needed; • held at the GSC Host Institution;
Board of Directors	• Quarterly meeting (face to face at mid-year); • Extraordinary Board meetings (e.g. if a Board decision is needed in the short term) can be convened at the request of the ED or any Board member. • Purpose is to formally adopt the ISARIC Annual Report and Annual Plan (at end-year) or discuss progress towards the targets set in Annual Plan and decision-making on any corrective measures or other issues that need a Board decision (at mid-year); • The Board meetings are Chaired by ISARIC Chair and organised by the GSC; • The Executive Director attends the Board meetings as non-deciding participant; • The face-to-face Board meeting at mid-year is held at a location of choice by the Board.
Member Assembly	• Annual face-to-face meeting; • Purpose is to network and to formally adopt the ISARIC Strategy; • Chaired by ISARIC Chair and co-Chairs; • Board of Directors, GSC staff and the AB is invited to join; • Hosted by one of the members of ISARIC. We strive to organise each annual MA meeting in a different Region every year.

Progress reporting

Fig. 16 depicts the annual reporting cycle in ISARIC, with the months in sync with the annual meeting and programming cycle of figures 14 and 15. Standard templates for the periodic reports will be developed by the GSC.

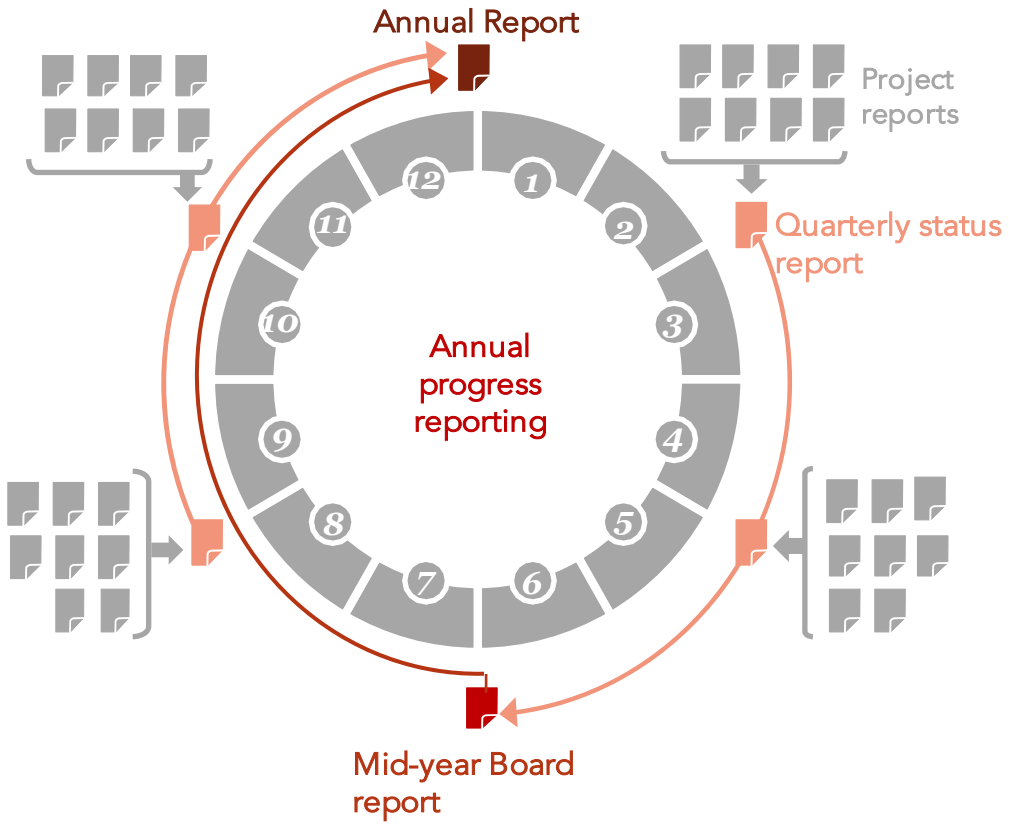


Figure 16: ISARIC annual reporting cycle

Project reports: frequency at least four times a year From Project Team to Executive Director

At the basis of the progress reporting are the periodic reports of the Project Teams responsible for the implementation of the ISARIC Projects. The frequency of the reporting should be at least four times a year and the timing should be in line with the Quarterly progress reporting. These Project Reports to the Executive Director provide a short status overview of the progress of the ISARIC Project towards its objectives and deliverables (behind schedule, on schedule, above schedule, met), budget utilisation and short comments on any setbacks, delays or other information that could be useful to the Executive Director.

Quarterly status reports: from Executive Director to the Board

The Project Reports form the input for the Quarterly Status reports from the Executive Director to the Board. The Quarterly Status report provides a comprehensive overview of the status of the ISARIC project portfolio. For each ISARIC Project the Quarterly progress report describes the status of the progress towards the overall goals and deliverables of the project, budget utilisation, and any issues or events that require Board attention.

Midyear Board report: from the Board of Directors to the Member Assembly

At mid-year, the Board produces its interim report to the MA, describing the progress made to date on the annual targets as set in the Annual Plan.

Annual Report: from ISARIC to the Members and external stakeholders

Each year the Board produces its Annual Report in which it informs its Members and external stakeholders about the activities and accomplishments of ISARIC in the past year.

Decision-making processes

This part describes the authority and decision-making procedures involved in key processes in ISARIC:

- Changes in the ISARIC Membership
- Changes in the ISARIC strategy
- Changes to the ISARIC project portfolio
- Changes in the ISARIC governance positions
- Changes in ISARIC policies

Below, the decision-making process and roles for the governance bodies involved is described for each of these processes. For this description, we make use of the RACI model in which four roles are distinguished:

- Responsible: this is the governance body that is responsible for preparing the decision and executing it.
- Accountable: the governance body that has the final authority to take the decision;
- Informed: the governance body that is informed of the progress and outcome of the decision (by the Responsible body)
- Consulted: the governance body that is consulted (by the Accountable body) prior to the decision making.

Governance Body	Default decision-making
Member Assembly	Decisions are made through voting. Each member has one vote. A decision needs a 60% majority. There are no veto-rights. Details are laid down in the ISARIC Members Agreement.
Board of Directors	Decisions are made based on consensus. If a consensus cannot be reached, decisions are put to vote, in which case a Board decision needs 7 out of 12 votes. There are no veto-rights. In case of equal votes, the ISARIC Chair decides.

Decisions regarding changes in ISARIC Membership

Selection of new Members

ISARIC is an inclusive federation, open to all clinical research networks on infectious diseases. The selection of new Members is a three-step process as depicted in figure 17.

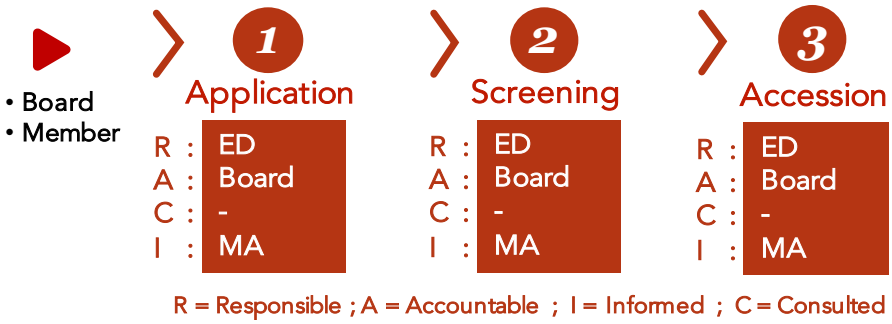


Figure 17: Decision process Member selection

- Trigger: Members and the Board continuously prospect for potential new Members, focusing on filling gaps in Regional coverage. If a prospective Member is identified, the Board is informed and Step 1 commences.
- Step 1 involves the Board deciding to request the prospective member to provide information needed to decide on its Membership. This includes information on its composition, its governance structure and work plans as well as any other information on the activities and plans of the network. The EDB executes this decision, develops and sends the application form and informs the MA of the process.
- Step 2 involves the screening of the information by the Board provided by the prospective Member on the compliance with the eligibility criteria. If the prospective Member complies with these criteria, step 3 commences.
- Step 3 is the formal decision by the Board to invite the candidate Member to accede to ISARIC. The ED prepares the accession of the new Member to the ISARIC Member Agreement. The MA is informed about the outcome. Once the Prospective Member has signed the Member Agreement, it is a formal Member of ISARIC with all rights and obligations attached.

Suspension of Members

Suspension of Members is a highly rare event. The Board can decide to suspend a Member in cases where a Member:

- does not comply anymore to the Member eligibility criteria (e.g. is no longer active);
- acts in breach of the ISARIC Member Agreement.
- or acts in a manner inconsistent with the mission, vision or values of ISARIC;

Suspended Members have no voting power in the MA and any representatives in the Board of the suspended Member also are automatically suspended (unless the person in question is also an active contributor to another not-suspended Member, in which case the person can continue to be part of the Board). The process of Member suspension is depicted in figure 18.

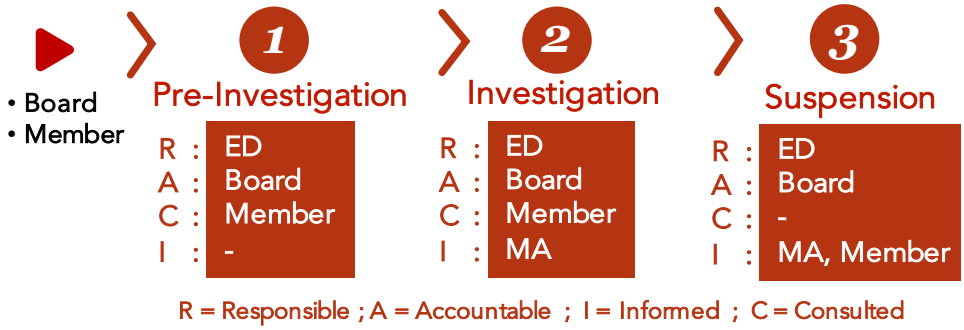


Figure 18: Decision process Member suspension

- Trigger: the decision-process on suspending a Member can be triggered by the Board or by any Member by formal request to the Board.
- Step 1: The Board decides, based on the information provided by the triggering party and after consulting the Member concerned (if possible/desirable) if a further investigation is warranted. If not, the process ends here. If the Board decides that a further investigation is warranted, step 2 commences.
- Step 2: The ED performs a further investigation into the grounds for suspension. In cases where these grounds are obvious (e.g. the Member has ceased its activities altogether) this step can be a short formal statement. In other cases (e.g. the Member is suspected of acting in breach with the Members Agreement) the investigation may involve several rounds of hearing the arguments in favour and against suspension. The MA is informed of the progress of the investigation.
- Step 3: In this final step, the Board decides on the suspension of the Member under investigation. Board members that are involved as partners in the Member have no voting rights in decisions regarding their suspension The ED prepares the Board decision and the MA is informed about the outcome.

Discharge of Members

Only suspended Members can be discharged. Discharge of a Member follows automatically if the Board is convinced that the grounds for suspension will not be resolved within six months following the decision to suspend the Member.
Discharged Members cease to be part of the MA and any representatives in the Board of the discharged Member also are automatically discharged (unless the person in question is also an active contributor to another Member, in which case the person can continue to be part of the Board).

Changes to the ISARIC Strategy and Governance Structure

Changes to the ISARIC Strategy

Changes to the ISARIC Strategy are implemented as part of the annual programming cycle described above. Changes to the ISARIC Strategy require an MA decision, according to the process depicted in fig. 19.

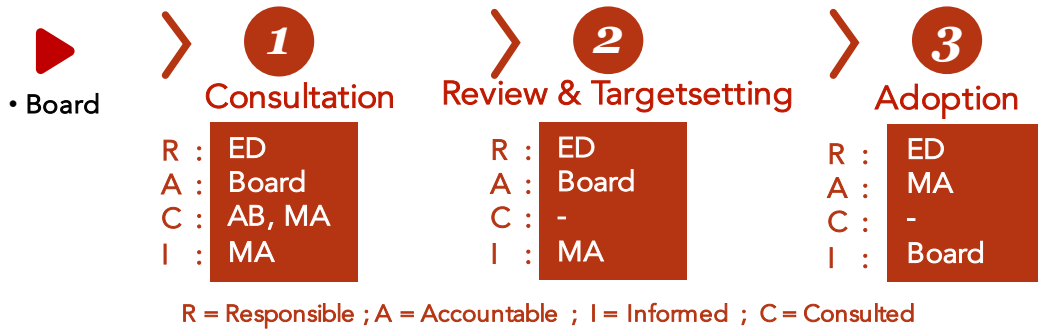


Figure 19: Decision process changes to organisational strategy

- Trigger: The Board triggers the annual review of the ISARIC Strategy as part of the annual programming cycle.
- Step 1 Consultation: The cycle starts with a round of consultations of the Members and Advisory Board (AB). Based on the progress reporting the Members and AB are asked to review the ISARIC Strategy and provide their comments and feedback.
- Step 2 Review and Target setting: based on the inputs received in the round of consultation the ISARIC Strategy is updated.
- Step 3: Adoption: the third step is the formal adoption of the updated ISARIC Strategy by MA vote.

Changes to the ISARIC Project portfolio

ISARIC Annual Plan

The development of the ISARIC Annual Plan is done as part of the annual programming cycle, according to the process depicted in fig. 20.

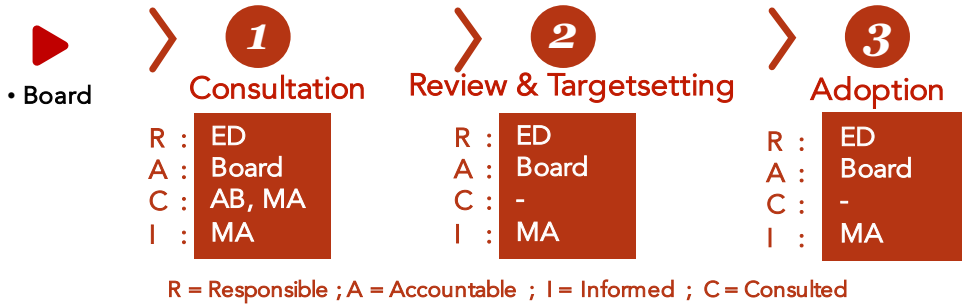


Figure 20: Decision process Annual plan development

- Trigger: The Board triggers the annual review of the ISARIC Strategy as part of the annual programming cycle.
- Step 1 Consultation: The cycle starts with a round of consultations of the Members and Advisory Board (AB). Based on the progress reporting the Members and AB are asked to provide their inputs for the annual targets and for the initiation/adaptation of (new) ISARIC Projects and/or Programmes in pursuit of these targets.
- Step 2 Review and Target setting: based on the inputs received in the round of consultation the Annual Plan is developed, with new targets for the internal goals and concrete suggestions for new or updated ISARIC Projects and Programmes.
- Step 3: Adoption: the third step is the formal adoption of the updated ISARIC Annual Plan by the Board.

Initiating new ISARIC Projects

The process of initiating new ISARIC Projects is depicted in fig. 21.

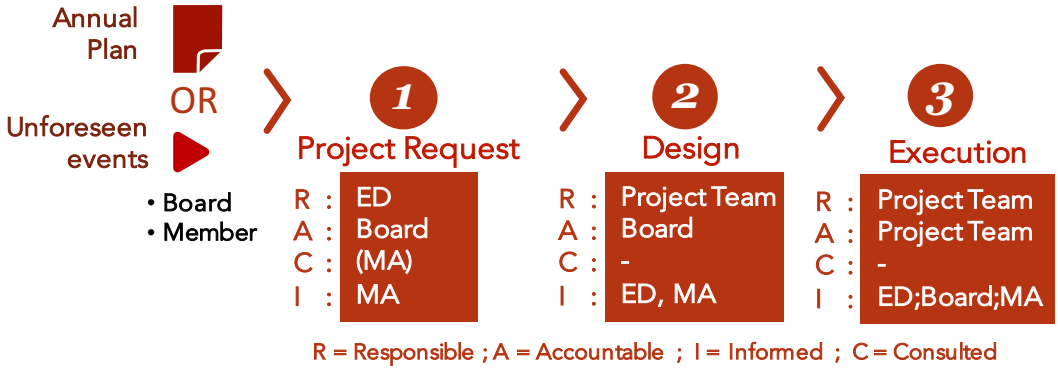


Figure 21: Decision process new ISARIC projects

- Trigger: The process of deciding on new ISARIC Projects can be initiated as part of the annual target setting in the Annual Plan or by any Member or the Board, in the case of unforeseen events not included in the Annual Plan (e.g. funding opportunities or an outbreak that warrants our response).
- Step 1 Project Request: This step involves the submission of a Project Request (template to be provided by the GSC) to the Board (via the ED). The Project Request presents briefly the proposed Project (goals, activities, partners, budget) on the basis of which the Board assesses the scientific and financial feasibility of the proposed project, the fit with the ISARIC Strategy and Annual Plan and the complementarity to the existing ISARIC Project portfolio. The Board consults (a group of) the MA, if required to form its opinion. If the Board gives permission to proceed, step 2 commences.
- Step 2 Design: This step involves the formation and installation of the Project Team responsible for designing the ISARIC Project according to the overall scope and goals of the ISARIC Project as included in the Annual Plan or Project Request. The resulting Project Plan forms the basis of the Execution and reporting phase of the ISARIC Project and contains information on the goals, activities, deliverables, milestones, planning and budgeted costs of the ISARIC Project.
- Step 3 Execution and Reporting: Step 3 is the execution and reporting of the ISARIC project under the responsibility of the Project Team.

Changes to ISARIC Projects

Any major changes to ISARIC Projects should be forwarded by the responsible Project Team to the Board. This includes changes to the ISARIC Project that may call into question the original decision to initiate the ISARIC Project (e.g. major changes to the project's goals, deliverables and budget).

Minor changes to ISARIC Projects fall within the authority of the Project Team.

Cessation of ISARIC Projects

There are several ways in which an ISARIC Project can be ended:

- The ISARIC Project has realised its objectives as planned: no decision-making needed.
- The ISARIC Project is ended at the request of the Project Team: in this case the SB decides if (parts of) the ISARIC Project can be continued under the responsibility of a new Project Team;
- The ISARIC Project is terminated by Board decision: this is a rare event in which the Board decides to terminate the ISARIC Project because it is of the opinion that the ISARIC Project is not implemented according to the original Project Request, has run out of budget, has lost its (scientific) relevancy or other events/issues have arisen that make continuation of the ISARIC Project impossible or undesirable.

Decisions regarding changes in ISARIC Governance

Changes to the ISARIC Governance structure

Suggestions for changes to the ISARIC governance structure can be initiated by the Board or by the MA. Changes to the ISARIC governance structure (e.g. expansion of the Board of Directors to 15 seats or the establishment of a legal entity) require an MA vote.

Election of the Board of Directors

Board members are elected by the MA. To ensure a smooth transition between Board elections, and to promote active Board participation from all Members, three Board seats are up for re-election every year, resulting in a maximum term of four years for each Board Member.

A Region is allowed a maximum of three seats in the Board. Regions already holding the maximum allowed number of seats cannot bring forward Board candidates in that year's Board election. The election process is organised into three steps as depicted in figure 22.

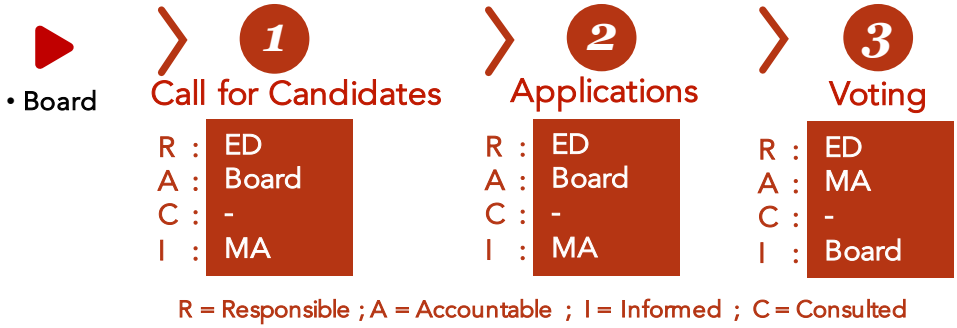


Figure 22: Decision process Board of Directors election

- Step 1: Call for Candidates - The Board publishes a Call for Candidates, inviting all Members to put forward candidates for the Board. The Call for Candidates informs the Members of the eligibility criteria and expected roles and responsibilities of Board members.

- Step 2: Applications - In response to the Call for Candidates, Members can put forward Board candidates. The Board screens the Applications on the criteria in the Call for Candidates and informs the MA of the full list of eligible candidates for voting.

- Step 3: Voting - Each Member votes a top 3 from the list of eligible candidates. The candidates are ranked based on the number of votes received from the MA. The top-ranking three candidates are appointed by the MA to serve on the SB for the next four years. In case of even votes, candidates from Regions not yet (or less) represented are ranked higher. In case the threshold of six Regions is not reached with the top 3) ranking candidates, the next top-ranking candidate(s) from other Regions are selected.

Election of the ISARIC Chair and vice-Chairs of the Board of Directors

The ISARIC Chair and vice-Chairs of the Board of Directors are elected by the Board members by voting. The Chair and vice-Chairs are all appointed for the full duration of their Board membership.

Appointment of the Executive Director

The Executive Director (ED) is appointed by the Board. In principle, the ED is a permanent position at the ISARIC Global Support Centre's Host Institution. In this case, the appointment of the ED is accompanied by an employment contract at the GSC Host Institution, in compliance with relevant national laws and in consultation with the employing organisation. However, the function of ED can also be fulfilled by externally hired interim staff. In these cases, the person in question is contracted by the GSC Host Institution for a definitive period as decided by the Board.

Appointment of staff at the Global Support Centre

The professional support staff at the Global Support Centre are selected and appointed by the Board in consultation with the ED and the GSC Host Institution that acts as the employer for the GSC staff.

Installing Advisory Board members

Advisory Board (AB) members are selected and appointed by the Board. In principle, AB members are appointed for indefinite terms. Only persons from outside ISARIC are eligible to serve on the AB.

Selection of the GSC Host Institution

To accommodate a smooth transition from the current ISARIC structure to the new structure, UOXF will be requested to remain ISARIC's GSC Host Institution. This designation of UOXF as the GSC Host Institution will be for a period of five years with re-election possible. New GSC Host Institutions are selected via the process as described below.

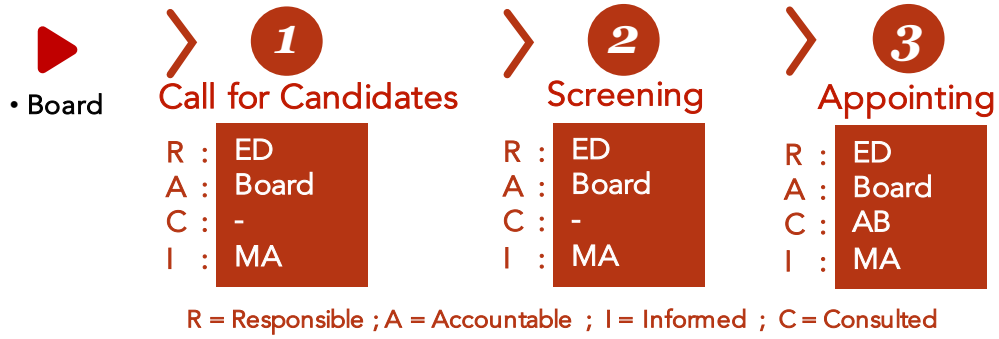


Figure 23: Decision process new Global Support Centre Host institution

- Trigger: The GSC Host Institution selection procedure is initiated if:
  - The five-year term of the current GSC Host Institution has ended
  - the GSC Host Institution is no longer capable of or willing to function as GSC Host Institution;
  - A majority of the MA decides in favour of the selection of a new GSC Host Institution;

- Step 1: The Board publishes a Call for GSC Host Institution candidates. Candidate GSC Host Institutions respond to the Board invitation by sending in a formal application to the Board. This can be several competing applications or one application. The MA is informed of the application(s) received and step 2 commences.
- Step 2: The Board screens the application(s) received on eligibility (e.g. active participant, operational capacity). If eligible the Board decides for the eligible candidate GSC Host Institution(s) to proceed to step 3. The MA and candidate GSC(s) is/are informed of this decision and step 3 commences.
- Step 3: step 3 is the formal voting by the Board on the appointing of the GSC Host Institution.

Annex 2: External Stakeholders

Patients and populations at risk

Patients (at risk of) infectious diseases outbreaks are the ultimate stakeholder of ISARIC. They form the recipient group of ISARICs purpose of reducing the morbidity and mortality of infectious disease outbreaks. At the individual level the interest of patients in ISARIC is the assurance of being provided with the best possible health interventions by their healthcare provider, based on the latest available scientific evidence, in case of outbreaks. At the population level the interest of patients at risk of outbreaks is the assurance of the public health authorities being empowered with the latest available clinical evidence in the design and implementation of outbreak prevention and control measures.

ISARIC members interact directly with this stakeholder group in the conduct of their clinical research studies. As participants in clinical research, they have a crucial role in and influence on ISARIC's core operations. As such, they need to be adequately informed and engaged in ISARIC activities.

Healthcare providers and health emergency responders

This stakeholder group is a primary user of the clinical research evidence and expertise generated by ISARIC. They are the primary target group of ISARIC in need of the best available clinical evidence to support their primary tasks of saving lives in case of (potential) outbreaks. This group encompasses the organizations and persons working in those organizations responsible for deciding on and implementing the patient-level health prevention and treatment strategies and associated supporting activities and communications prior to and in the event of infectious disease outbreaks.

This includes primary, secondary and tertiary hospitals and clinics and their staff, community organizations and groupings (e.g. community groups and religious groups) and non-governmental organizations and charitable foundations with an active role in (health) emergency response. Examples are Médecins Sans Frontières, Save the Children, Oxfam and ALIMA.

Government public health authorities and regulators

This stakeholder group is also a primary user of the clinical research evidence and expertise generated by ISARIC. It includes local, national and international governmental organisations/authorities that are responsible for designing and implementing appropriate population level prevention and control strategies against infectious diseases outbreaks.

This stakeholder group includes municipalities or equivalents at the local level, Ministries of Health, national public health authorities/national centres of diseases control or equivalents at the national level and the WHO and its regional offices, European Commission Directorate-Generals (e.g. DG Research, DR SANTE), African Union (and its Planning and Coordinating Agency NEPAD), European CDC, at the international level.

It also includes health (research) regulators at the national level such as the Food & Drug Administration in the USA and the National Competent Authorities (NCA) and international level (e.g. the European Medicines Agency (EMEA) in Europe, the African Medicine Agency (AMU, to be established) in Africa).

Health research community

This group is made up of the international (academic) research community focusing on infectious diseases research and related fields of research. It includes (networks of) academic research groups and private research organisations spanning from fundamental, pre-clinical research to clinical research and education. They are the (potential) partners and collaborators of the members of ISARIC and share a scientific and societal interest in combating infectious diseases through the accumulation of new knowledge and technology.

Health research funders and commissioners

The second external stakeholder group of ISARIC are the health research funders and commissioners. These are the (partnerships of) public and private sectors organisations that fund and/or commission clinical research on infectious diseases.

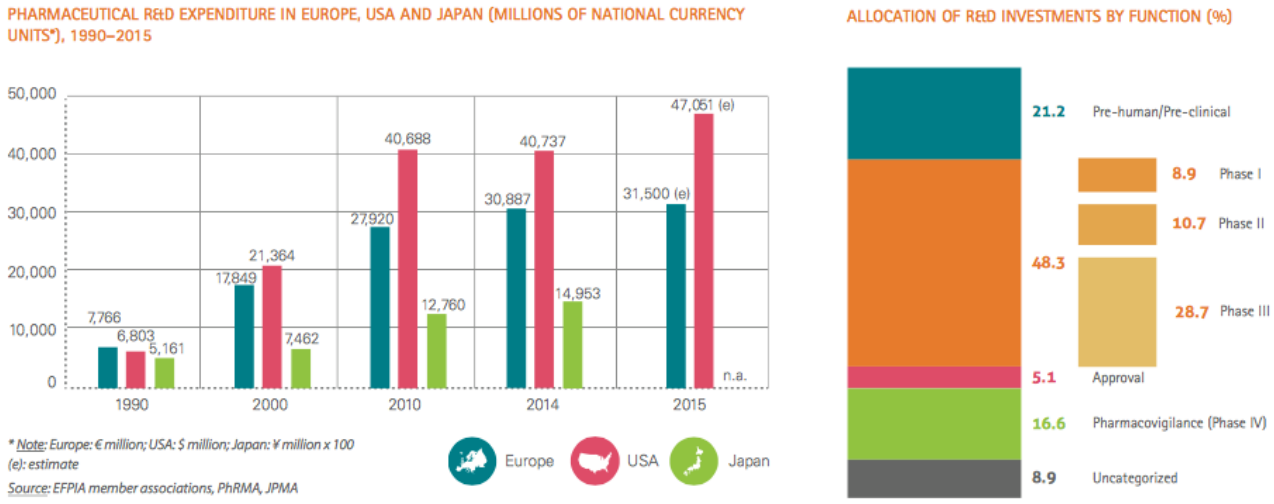
In the non-commercial sector this includes public sector organisations such as the European Commission (EC) Directorate General (DG) Research, Medical Research Council (MRC) and private charitable organisations such as The Wellcome Trust and the Bill and Melinda Gates Foundation, which have all funded ISARIC activities. Besides these examples, there are numerous national and international R&D funders active in the field of infectious diseases research such as National Institutes of Health (NIH), Biomedical Advanced Research and Development Authority (BARDA), Institute Pasteur, and the Canadian Institutes of Health Research (CIHR) and many others.

In 2014, international funders of preparedness and response research founded GloPID-R (Global Research Collaboration for Infectious Disease Preparedness: see www.glopid-r.org). Members of GloPID-R include the EC DG Research and the Wellcome Trust and various national funders (for full list see: https://www.glopid-r.org/learn-about-us/members/). The Secretariat of GloPID-R Sec is co-located at the University of Oxford and Fondation Mérieux. GloPID-R does not fund research directly but rather coordinates and shares information among the funding organizations to ensure that research capacity and capabilities are in place to support the conduct of scientific research. These public and private health research funders directly or indirectly supply the majority of the funding for the activities by ISARIC. Their interest in ISARIC is as an operational research federation that can contribute to the realization of their policy objectives.

In the commercial sector the R&D commissioners include the pharmaceutical and medical technology industry. The pharmaceutical industry invests about USD 92 billion per year (2011) on

R&D, of which about USD 50 billion is in the United States, 11.5 billion in Japan, 5.2 billion in Germany and 3.7 billion in France[2].

According to EFPIA the R&D expenditures have increased steadily of the last five years. Almost half of the R&D expenditure is made on Phase I, II and III trials. Public and private R&D funders are increasingly collaborating in health R&D in joint Public Private Initiatives. The Innovative Medicines Initiative (IMI) is Europe's largest public-private partnership (see www.imi.europa.eu) that funds a plethora of public-private R&D projects aimed at the development of innovative medicines. Amongst these are several of the Ebola trials through its Ebola + programme, which was launched in response to the Ebola outbreak in West Africa in 2014, with a total budget of over €200 million.



Source: PhRMA, Annual Membership Survey 2016 (percentages calculated from 2014 data; total values may be affected by rounding)

Another recent example of a public private initiative in infectious diseases research preparedness and response is the establishment of the Coalition for Epidemic Preparedness Innovations (CEPI), which was founded by the Government of Norway, India, The Wellcome Trust, the Bill & Melinda Gates Foundation and the World Economic Forum and partners with several private sector organizations including pharmaceutical industry, NGOs and academia. CEPI seeks to stimulate and accelerate the development ("just-in-case") and ("just-in-time") vaccines and associated development platforms and institutional capacities.

Media

The traditional media (newspapers, television, radio) and social media (e.g. Twitter, Instagram, Reddit, Facebook, Qzone, YouTube) have an enormous impact on outbreak preparedness and

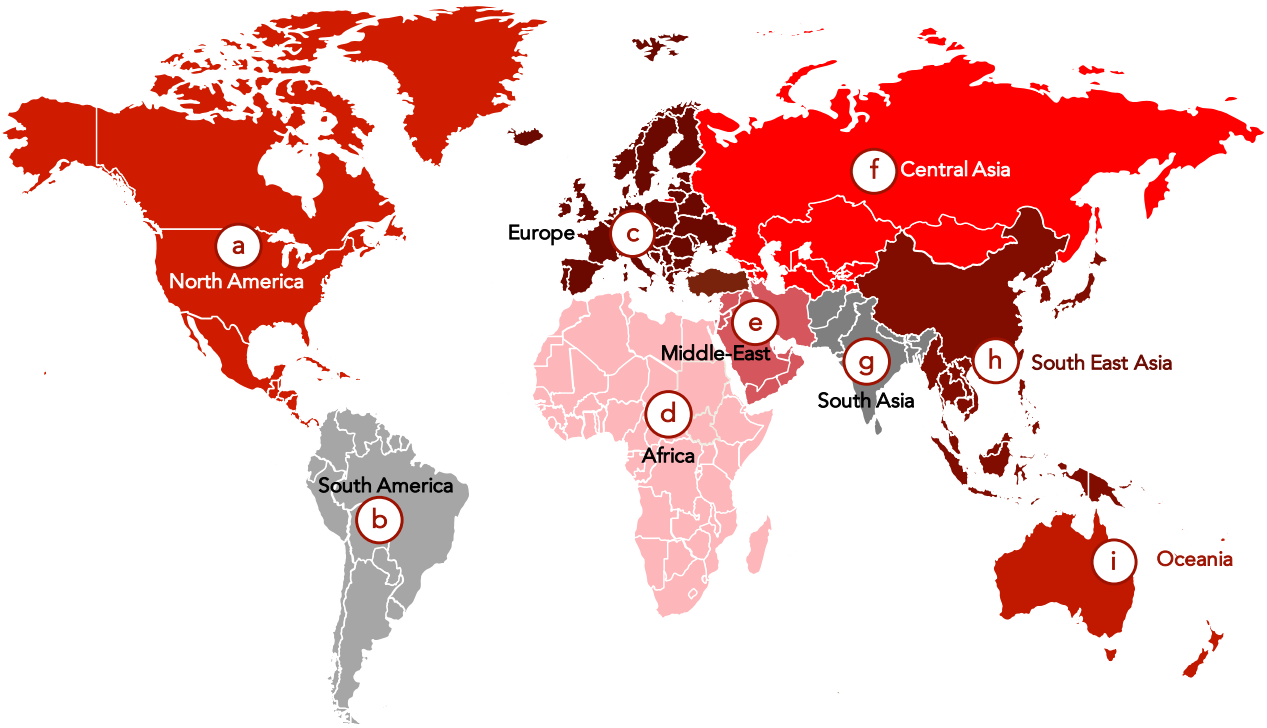
[2] OECD, Health at a Glance 2015.

response. They can act both as catalyst or barriers to the effective implementation of clinical research preparedness and response actions and the subsequent use of the clinical research evidence in patient level and population level prevention and control measures. Risk communication and adequate information sharing with the public is therefore of crucial importance to the purpose and mission of ISARIC.

In addition, the scientific journals form an important partner for ISARIC in the design and implementation of clinical research and the dissemination of its results and communicating with the scientific community through fast-track open access publications.

Annex 3: Countries List per Region

ISARIC distinguishes nine Regions:



a. North-America

Antigua and Barbuda
Bahamas
Barbados
Belize
Canada
Costa Rica
Cuba
Dominica
Dominican Republic
El Salvador
Grenada
Guatemala
Haiti
Honduras
Jamaica
Mexico
Nicaragua
Panama
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Trinidad and Tobago
United States

b. South America

Argentina
Bolivia
Brazil
Chile
Colombia
Ecuador
Guyana
Paraguay
Peru
Suriname
Uruguay
Venezuela

c. Europe

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Liechtenstein
Lithuania
Luxembourg
Macedonia
Malta
Moldova
Monaco
Montenegro
Netherlands
Norway
Poland
Portugal
Romania
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Turkey
Ukraine
United Kingdom
Vatican City

d. Africa

Algeria
Angola
Benin
Botswana
Burkina
Burundi
Cameroon
Cape Verde
Central African Republic
Chad
Comoros
Congo
DR of Congo
Djibouti
Egypt
Equatorial Guinea
Eritrea
Ethiopia
Gabon
Gambia
Ghana
Guinea
Guinea-Bissau
Ivory Coast
Kenya
Lesotho
Liberia
Libya
Madagascar
Malawi
Mali
Mauritania
Mauritius
Morocco
Mozambique
Namibia
Niger
Nigeria
Rwanda
Sao Tome and Principe
Senegal
Seychelles
Sierra Leone
Somalia
South Africa
South Sudan
Sudan
Swaziland
Tanzania
Togo
Tunisia
Uganda
Zambia
Zimbabwe

e. Middle-East

Bahrain
Iran
Iraq
Israel
Jordan
Kuwait
Lebanon
Oman
Qatar
Saudi Arabia
Syria
United Arab Emirates
Yemen

f. Central-Asia

Kazakhstan
Kyrgyzstan
Mongolia
Russian Federation
Tajikistan
Uzbekistan

Turkmenistan

g. South-Asia

Afghanistan
Bangladesh
Bhutan
India
Maldives
Nepal
Pakistan
Sri Lanka

h. South-East Asia

Brunei
Burma (Myanmar)
Cambodia
China
East Timor
Indonesia
Japan
North Korea
South Korea
Laos
Malaysia
Philippines
Singapore
Thailand
Vietnam

i. Oceania

Australia
Fiji
Kiribati
Marshall Islands
Micronesia
Nauru
New Zealand
Palau
Papua New Guinea
Samoa
Solomon Islands
Tonga
Tuvalu
Vanuatu

Annex 4: ISARIC at a glance: 2011-2017

ISARIC brings together **55** international, national and local networks, and **39** individual members whose research activities span **112** countries worldwide. Their commitment to ISARIC's vision has delivered over **18,000** volunteer hours to realise ISARIC activities.

Our key achievements

- Provided a communications platform during outbreaks to clinical researchers, clinicians, industry, national and international public health bodies, and NGOs:
  - MERS-CoV Working Group: **20** teleconferences, **60+** participants.
  - Ebola Working Group: **20** teleconferences, **100+** participants
  - Zika Working Group: **24** teleconferences, **100+** participants.
- Connected members and partners as collaborators for funding proposals and collaborative projects (including SPRINT-SARI and ZIKAlliance).
- Actively sought new partnerships in LMICs to enable the exchange of knowledge, ideas and capacity.
- Communicated and disseminated a Weekly News Round-up to over **400** subscribers.
- Facilitated rapid responses to outbreaks by offering operational, administrative, technical and project management support to members and partners.
- Supported the on-going work of the Rapid Assessment of Potential Drugs and Interventions for Ebola (RAPIDE) clinical trials in West Africa.
- Supported GloPID-R's data sharing and clinical trials networks working groups as part of the GloPID-R Secretariat.
- Worked with WHO and other partners on standardising and harmonising Zika tools and data, including six epidemiological research protocols.
- Contributed to the establishment of regional preparedness networks in Europe (PREPARE), Australia (APPRISE), Africa (ALERRT), and Latin America (REDe).
- Coordinated the development of the ISARIC-WHO Clinical Characterization Protocol for Severe Emerging Infections, which is approved, adaptable, and openly accessible
- Coordinated the development of standardised open access data collection tools to facilitate clinical research for MERS-CoV, Ebola and Zika.
- Rolled out SPRINT-SARI, a global observational study of SARI, enrolling more than **1,200** patients in **135** sites, in **24** countries, on **6** continents.
- Contributed to the development of a Global Randomised Adaptive Clinical Trial Programme for SARI (GACT-SARI)
- Leading the Global Outbreak Alert & Response Network Research Sub-group.

Find out more about us on our website http://www.isaric.org or through our social media presence as @ISARIC1 on Twitter, Facebook, or LinkedIn.

Annex 5: Strategy Review Group and Project Team

Strategy Project team

Peter Horby	ISARIC Chair
Gail Carson	ISARIC Coordinating Centre
Sarah Moore	ISARIC Coordinating Centre
Frank Deege	nextco

Strategy Review Group

John Amuasi	Ghana	Senior Research Fellow and Executive Director for the African Research Network for Neglected Tropical Diseases (ARNTD). Kumasi Center for Collaborative Research in Tropical Medicine (KCCR), Ghana
Yaseen Arabi	Kingdom of Saudi Arabia	Professor, King Saud Bin Abdulaziz University for Health Sciences
Lucille Blumberg	Republic of South Africa	Deputy-Director: Epidemiology & Medical Consultant, Centre for Emerging and Zoonotic Diseases.
Fernando Bozza	Brazil	Head of the Critical Care of the National Institute of Infectious Disease, Oswaldo Cruz Foundation, Ministry of Health.
Zhancheng Gao	People's Republic of China	Chief, Department of Respiratory and Critical Care Medicine Peking University People's Hospital.
Kathryn Maitland	Kenya	Professor of Paediatric Tropical Infectious Diseases at the Faculty of Medicine Imperial College, London, Director of the ICCARE at the Institute of Global Health Innovation, Imperial College, London and an Honorary Fellow at MRC Clinical Trials Unit, University College, London.
John Marshall	Canada	Professor of Surgery at the University of Toronto, and a Trauma Surgeon and Intensivist at St. Michael's Hospital in Toronto, Canada. Inaugural chair of the International Forum for Acute Care Trialists (InFACT)
Kathy Rowan	United Kingdom	Honorary Professor in the Department of Health Services Research and Policy at the London School of Hygiene & Tropical Medicine and in the Division of Research Strategy at University College London, Director at Intensive Care National Audit & Research Centre (ICNARC)
Steve Webb	Australia	Senior Staff Specialist in Intensive Care Medicine at Royal Perth Hospital, Clinical Professor of Critical Care Research in the Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University. InFACT Vice-Chair.

Strategy Review Group meetings

Workshop 1	20 December 2016	Lucille Blumberg, Fernando Bozza, John Marshall, Steve Webb
	21 December 2016	John Amuasi, Zhancheng Gao,
	11 January 2017	Yaseen Arabi, Kathryn Maitland, Kathy Rowan
Workshop 2	7 April 2017	John Amuasi, Yaseen Arabi, Lucille Blumberg, Fernando Bozza, John Marshall, Kathy Rowan, Steve Webb

Annex 6: List of Interviewees

Tamuna Akhvlediani	US medical research directorate, Georgia
Buddha Basnyat	Oxford University Clinical Research Unit- Nepal
Roberto Bruzzone	HKU-Pasteur Research Centre, Hong Kong PR China
Nick Day	Mahidol Oxford Tropical Medicine Research Unit, Thailand
Dean Everett	University of Liverpool, WT Malawi
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