



**STAR-IDAZ**  
International Research  
Consortium on Animal Health

# International Research Consortium (IRC)

## POLICIES & GUIDELINES



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## A. INTRODUCTION

Animal diseases can cause serious social, economic and environmental damage and in some cases also threaten human health. An increasing number of the major disease problems or threats faced by the livestock industry are of a global nature. The associated risks have increased over recent decades, especially as a result of the increased globalisation of trade and animal product movements, and the consequent transfer of associated fast evolving pathogens. These changes are exacerbated by interaction with environmental change, including changes to land use and the potential variabilities associated with climate change. Global challenges need global solutions and these can only be achieved in the required timeframe through a common research effort. For animal disease research, coordination of efforts is key to success, in order to maximize the output from investments in research. Improved coordination of, and international collaboration in, current research activity is needed to ensure the efficient and effective underpinning of national policies regarding trans-boundary and other animal diseases (including zoonoses) and the sustainability of the livestock and animal health industries

The aims of “Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses” (STAR-IDAZ) are to strengthen the linkages between and reduce the duplication of global research effort, maximise the efficient use of expertise and resources and accelerate coordinated development of control methods at the international level. To achieve this an international forum of R&D programme owners/managers and international organisations was established for the purpose of sharing information, improving collaboration on research activities and working towards common research agendas and coordinated research funding on the major animal diseases affecting livestock production and/or human health. The scope of the project included coordination of research relevant to emerging and major infectious diseases of livestock, including fish and managed bees, and those infections of livestock that may carry the risk of disease threat to human health. Diseases of wildlife are also considered where they were identified as reservoirs of infection with emerging and major infectious diseases of humans or production animals. The specific objectives of the global network are to:

- Strengthen the linkages between and reduce the duplication of global research effort on high priority infectious diseases of animals (including zoonoses) maximise the efficient use of expertise and resources and accelerate coordinated development of control methods.
- Identify and co-ordinate the response to gaps in research activities for targeted diseases.



- Create the necessary critical mass and capacity to address emerging infectious disease threats.
- Improve the cost-effectiveness and added value to network partners of current research programmes.
- Develop durable procedures for a better co-ordinated, rapid response to urgent research needs.
- Identify unique regions with localised diseases and improve access to research in those areas.
- Improve access to and the utility of research results across all partner organisations.
- Facilitate the establishment of research management capacity and programmes in those partner countries wishing to develop research activities in this area.

The long term objective of the Global Network is the creation of an open network of mutually accessible and complementary research programmes able to respond to regional and global challenges, creating the tools for improved control of the major animal diseases threatening the livestock industries and/or of public health concern by bringing forward joint research programmes on major infectious diseases of livestock. STAR-IDAZ was successful in establishing, through its global and regional activities, a network of organisations managing research budgets or programmes in approximately 50 countries who are committed to working together.

Nine priority diseases and three cross-cutting issues were identified by members including Influenza, Mycobacterial Diseases, Foot and Mouth Disease (FMD), Salmonella, Helminth Parasites, Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), Brucellosis, African Swine Fever (ASF), Rabies, Alternatives to Antibiotics, Vaccinology and the Role of Livestock Diseases in Greenhouse Gas Emissions. Working Groups have been or are being established with research gaps analyses published on the STAR-IDAZ website as they become available.

The development of an agreed Data Sharing Statement is helping to ensure that well-documented datasets are available for secondary analysis, the capacity to manage and analyse data is strengthened, published work and data are linked and archived, and data sharing is sustainably resourced for the long term.

The STAR-IDAZ IRC will build on this by streamlining access to relevant information, harmonized data and samples and improve coordination of research activities on priority topics. It will stimulate and coordinate basic and applied research, by promoting links between existing resources, and encouraging translational, strategic and applied research. Furthermore, it is essential to strengthen the links between academia and industry, so that industry better capitalizes on strong academic research results to translate these into new diagnostic tools, vaccines, therapeutic and disease control strategies. It will enable the development of a durable coordinated research effort on the major infectious diseases (including production-related diseases and zoonoses) of animals (including aquatic animals) by involving existing and future key players through:

- Greater sharing of information between (trans)national programmes.



- Development of links between ongoing research programmes on priority diseases, with sharing of information and resources and creation of critical mass.
- Better coordination of existing national programmes across the partner organisations.
- Development of a common agenda based on identified, shared priorities.
- Building animal health research capacity by addressing identified gaps in research capacity to ensure adequate provision globally.

Benefits will include:

- Efficient deployment of national funds for both national and trans-national (joint) research, including research procurement in response to emergency situations.
- Improved cost-effectiveness of commissioned research, by creating a consensus on the level of funding that should be directed at given priorities of both nationally and internationally funded programmes.
- Improved coordination of research priorities suitable for future funding
- Improved availability of validated and relevant research data for animal health policy makers and the animal health and livestock industries (including aquaculture).
- Improved availability of information on national research capacity, including expertise, in the various areas.
- Improved consultation with other international policy-makers and animal health organisations (e.g. EFSA, ECDC, OIE, FAO, and WHO).
- Faster development of the needed control tools for animal disease



## **B. ESTABLISHING THE CONSORTIUM**

Maximizing scarce resources and coordinating research efforts are key to success in the animal diseases field. STAR-IDAZ is a global network of animal disease research funders and programme owners established in 2011 as the EU-financed STAR-IDAZ Coordination and Support Action project to improve coordination of research activities on the major infectious diseases of livestock and zoonoses so as to hasten the delivery of improved control methods. STAR-IDAZ involved partners from 16 countries around the world with organisations from more than 30 other countries involved at a regional level through networks established for the Americas, Asia and Australasia and Africa and the Middle East to complement the existing European network. The networks of research funders and scientists that were established at the global, regional and priority disease level are leading to improved communication, coordination and efficiency of animal disease research.

STAR-IDAZ Members have now signed a Memorandum of Understanding outlining the relationship between the Parties (normally animal health research programme owners and funders and related global or regional bodies), representing the transformation of the EU-financed STAR-IDAZ Coordination and Support Action into a self-sustainable network. To move research coordination to another level the European Commission's Agriculture Directorate and the STAR-IDAZ partners are establishing an International Research Consortium to ensure that synergies and complementarities of animal disease research at an international level can be achieved.

A workshop was held in Brussels, on 1 and 2 October 2015 where the governance of the initiative and the goals to deliver, by 2022, were discussed and agreed. The make-up of the STAR-IDAZ IRC Scientific Committee has been established and XX working groups were formed.

The latest information concerning the state of play for STAR-IDAZ can be found at the following website: <http://www.star-idaz.net/>



## C. CONSORTIUM GOALS

### Objectives and deliverables of the STAR-IDAZ International Research Consortium (IRC)

The overarching objective of STAR-IDAZ IRC is to coordinate research at international level to contribute to new and improved animal health strategies for at least 30 priority diseases/infections/issues

The deliverables include:

- candidate vaccines, and/or
- diagnostics, and/or
- therapeutics and other animal health products, and/or
- procedures and/or
- key scientific information/tools to support risk analysis and disease control

The DISCONTTOOLS project considered the products available for the control of 52 diseases, highlighting gaps in available diagnostics and vaccines and the research needs to address these gaps. STAR-IDAZ partners identified nine diseases for initial collaboration. OIE has now identified a range of diseases of pigs, poultry and farmed fish where new or improved vaccines would have greatest impact in reducing antibiotic usage. The priority diseases/infections/issues selected by STAR-IDAZ IRC partners will include those diseases having a major impact on productivity, threatening international trade, where new vaccines would have greatest impact in reducing use of antibiotics and those infections of animals that pose a risk to human health. A proposed initial list included Influenza, Bovine Tuberculosis, Foot and Mouth Disease, Brucellosis, African Swine Fever, Vector-borne diseases, Coronaviruses, Mastitis, Helminths, Rabies, Respiratory Diseases of Pigs and Anti-microbial resistance but it is recognised that some of the challenges can be addressed best as cross-cutting issues such as the needed improvements in vaccine technologies and Working Groups will be established to consider these.

### 1) Vaccines.

The consortium will develop all the necessary measures and policies to facilitate the development of new vaccines for animal diseases including encouraging researchers to engage with the pharmaceutical industry at an early stage in the development of prototype vaccines so as to assist knowledge/technology transfer.

Depending on the current state of play of each disease the research needed, which will be established by gap analysis, may include critical underpinning scientific needs such as the identity of protective antigens, virulence factors and correlates of protection.



However many of the needs relate to generic vaccine technology and are not disease specific including the need for improved adjuvants and vectors.

## **2) Diagnostics.**

In conjunction with industry efficient, multi-purpose, including pen-side, diagnostic tests for animal diseases will be developed.

Avenues that will be exploited include:

the use of "omics" and other approaches to identify biomarkers of infection, including subclinical infection.

## **3) Therapeutics.**

Therapeutic targets will be identified including alternatives to antibiotics.

## **4) Disease control strategies.**

Areas to be considered will include genetic markers of resistance, mathematical models of disease spread and intervention strategies, and key information to support risk analysis and disease control as required by policy/decision makers.

To support those goals, and streamline processes beyond 2022, the consortium will also strengthen international cooperation in a number of enabling areas. The consortium will:

- a. support top-quality basic research for better understanding host pathogen interactions, including basic immunology and its application in vaccinology.
- b. support the development of mathematical models of intervention strategies.
- c. support the development and use of adequate disease classification in multifactorial clinical outcomes.
- d. make data accessible to the entire research community as rapidly as possible, and with minimal restrictions. The consortium will work towards establishing common bioinformatics tools and standards that will ease networking between data centres
- e. set up an efficient structure that will coordinate this international effort so that the interests and priorities of individual participants, self-organizing consortia, funding agencies and nations are addressed.
- f. The consortium will encourage the minimization of redundancy between the different projects around the world.



- g. establish a strong dissemination and communication plan to all potential stakeholders.

## **D. CONSORTIUM POLICIES AND GUIDELINES**

Objectives of a consortium policy and guidelines document:

**A consortium policy** is a principle which consortium members agree to follow. Although policies will likely be long-lasting, STAR-IDAZ IRC will periodically review its policies.

**Consortium guidelines** refer to recommendations made by STAR-IDAZ IRC scientific committees/working groups that offer advice as to “best practices” at a given time. Considering the rapid evolution in technologies and new knowledge gained guidelines are likely to evolve in the coming years.

The STAR-IDAZ IRC Scientific Committee will be the "guardians" of updating this policy document, and propose changes to the Executive Committee for adoption. The Scientific Committee will work closely with the working groups to ensure that policies and guidelines are relevant and implemented.

The STAR-IDAZ IRC policies and guidelines document should be communicated widely, and contain sufficient information to allow funding bodies and scientists in many countries to make decisions on future participation.

### **Policy and guidelines for researchers**

Researchers involved in STAR-IDAZ IRC associated projects are expected to comply with the following policies and guidelines:

#### **Sharing and collaborative work in animal disease research**

##### ***Policies:***

Animal Disease research should be collaborative. Resources, data and results should be shared among STAR-IDAZ-IRC research projects and made publicly available to the broader community, and duplication should be avoided.

Data producers acknowledge their responsibilities to release data rapidly and to publish initial analyses in a timely manner.

Animal disease biobanks (microbiological collections, tissues and other animal materials) should aim to be global in geographic scope and practice.

Sharing and distributing of biomaterials among animal disease biobanks is highly encouraged.



***Guidelines:***

Data generated from research projects, including source data, should be deposited in appropriate open or controlled access public databases.

IP issues and confidentiality agreements need to be balanced with the need to share information for the benefit of research.

Information about STAR-IDAZ IRC and associated research projects should be disseminated and made available to the animal disease communities and the public.

Animal disease research should be published even where its outcomes are negative or do not show convincing results, including clinical trials.

Research publications should appropriately acknowledge research funding and the use of infrastructures such as biobanks.

**Good Research Practice**

STAR-IDAZ IRC partners expects the researchers it funds to adhere to the highest standards of integrity. To facilitate this the Guidelines on Good Research Practice included below have been adopted.

Institutions are expected to have in place their own published standards of good research practice and the adoption of procedures for the investigation of allegations of research misconduct is encouraged.

***Policies:***

International, national, regional and local legislation/regulations need to be adhered to with respect to data protection and ethical approvals.

Research projects should adhere to standard practices endorsed by STAR-IDAZ IRC.

Research projects should publish their results in a timely manner in peer-reviewed scientific journals, preferably with open access.

***Guidelines:***

STAR-IDAZ IRC cannot be prescriptive about individual approaches taken by researchers to solving particular research problems. However it is expected that institutions will ensure that an adequate structure exists to promote and promulgate good research practice, emphasising integrity and



rigour in research, and to create a culture in which the following general principles can be understood and observed.

### **1. Integrity**

- Researchers should be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research work, including experimental design, generating and analysing data, applying for funding, publishing results, and acknowledging the direct and indirect contribution of colleagues, collaborators and others.
- Plagiarism, deception or the fabrication or falsification of results should be regarded as a serious disciplinary offence.
- Researchers are encouraged to report cases of suspected misconduct and to do so in a responsible and appropriate manner.
- Researchers should declare and manage any real or potential conflicts of interest.

### **2. Openness**

- While recognising the need for scientists to protect their own research interests, STAR-IDAZ IRC expects the researchers it funds/manages to be as open as possible in discussing their work with other scientists and with the public in order to help foster an informed public climate within which biomedical science can flourish.
- Once results have been published, STAR-IDAZ IRC expects researchers to make available relevant data and materials to other researchers, on request, provided that this is consistent with any ethics approvals and consents that cover the data and materials and any intellectual property rights in them.
- STAR-IDAZ IRC recognises that publication of the results of research may need to be delayed for a reasonable period pending protection of intellectual property arising from the research. Any such periods of delay in publication should, however, be kept to a minimum.

### **3. Guidance from professional bodies**

- Where available, STAR-IDAZ IRC expects researchers to observe the standards of research practice set out in guidelines published by scientific and learned societies, and other relevant professional bodies.
- All researchers should be aware of the legal requirements that regulate their work.



- Professional bodies should endeavour to influence public decision makers to be open to new technologies.

#### **4. Primary data/samples**

- There should be clarity at the outset of the research programme as to the ownership of, where relevant:
  - data and samples used or created in the course of the research
  - the results of the research.
- Researchers should keep clear and accurate records of the procedures followed and the approvals granted during the research process, including records of the interim results obtained as well as of the final research outcomes. This is necessary not only as a means of demonstrating proper research practice, but also in case questions are subsequently asked about either the conduct of the research or the results obtained.
- Data generated in the course of research should be kept securely in paper or electronic format, as appropriate. STAR-IDAZ IRC considers a minimum of ten years to be an appropriate period.
- Back-up records should always be kept for data stored on a computer.
- Institutions should have guidelines setting out responsibilities and procedures for the storage and disposal of data and samples (including compliance with the requirements of any ethics committee).

#### **5. Ethical practice**

##### *5.1 Research involving animals*

- Research involving animals should have approval through the appropriate ethical review processes, taking into account national requirements and those of the funding bodies.
- Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for reduction, replacement and refinement of animal involvement (the three Rs) and ensure that the experimental design is robust enough to deliver significant results.

##### *5.2 Risks of research misuse*

- In progressing their scientific investigations, researchers should actively consider any risks that their research will generate outcomes that could be misused for harmful purposes. Where such risks exist, they should seek advice and take active steps to minimise them.



- Institutions should have in place mechanisms to ensure that risks of misuse associated with ongoing research programmes are identified and managed, and to provide advice to the researchers that they employ on these issues.

## **6. Publication practice**

- Results should be published in an appropriate form, usually as papers in refereed journals.
- Anyone listed as an author on a paper should accept responsibility for ensuring that he/she is familiar with the contents of the paper and can identify his/her contribution to it. The practice of honorary authorship is unacceptable.
- The contributions of formal collaborators and all others who directly assist or indirectly support the research should be properly acknowledged.

## **Data Management and Sharing**

STAR-IDAZ partners are committed to ensuring that the outputs of the research it funds/manages, including research data, are managed and used in ways that maximise public benefit. Making research data widely available to the research community in a timely and responsible manner ensures that these data can be verified, built upon and used to advance knowledge and its application to generate improvements in animal health.

We believe that success in maximising the value of research data depends crucially on fostering a culture in which both data generators and data users adopt good research practice, and act with integrity and transparency in managing, using and sharing research data. Researchers, research institutions, resource providers, funders and publishers all have important roles to play in helping to develop this enabling environment and in developing the resources and systems required.

There is a growing international consensus on the need to preserve and share research datasets in a manner that maximises their long-term value. This has been articulated in key documents such as the OECD Principles and Guidelines for Access to Research Data from Public Funding (2007); the Fort Lauderdale Principles (2003) and the Toronto Statement (2009).

Our policy on data management and sharing reflects the principles set out in these statements and is consistent with the [Data Sharing Statement](#) adopted by STAR-IDAZ partners

### ***Policy statement***

1. STAR-IDAZ IRC expects all of its funded researchers to maximise the availability of research data with as few restrictions as possible.
2. Approach for managing and sharing data should be addressed at the research proposal stage, with inclusion of a data management and sharing plan in cases where the proposed research is



likely to generate data outputs that will hold significant value as a resource for the wider research community. Funding bodies should review data management and sharing plans, and any costs involved in delivering them, as an integral part of the funding decision and work with grant holders on an ongoing basis to support them in maximising the long-term value of key datasets resulting from their research.

3. STAR-IDAZ IRC expects all users of research data to acknowledge the sources of their data and to abide by the terms and conditions under which they accessed the original data.

4. STAR-IDAZ partners should foster an environment that enables researchers to maximise the value of research data, working in partnership with others to i) ensure that key data resources are developed and maintained for use by the research community; ii) recognise the contributions of researchers who generate, preserve and share key research datasets and iii) develop best practice for data sharing in different fields - recognising that different data types raise distinct issues and challenges.

## **Intellectual Property and Patenting**

The mission of STAR-IDAZ is to foster and promote research with the aim of hastening the delivery of new and improved tools and strategies for the control of animal disease. This is the driving force behind and the basis for its policy on the protection and use of intellectual property rights. The aim of this policy is to provide a clear statement for STAR-IDAZ IRC-supported scientists on STAR-IDAZ IRC position on the protection and use of intellectual property through patents.

In developing this policy, STAR-IDAZ IRC has considered a wide range of issues, in particular the role of intellectual property rights in creating the best conditions for research and in translating that research into tangible benefits for animal health and the livestock and animal health industries. STAR-IDAZ IRC supports the appropriate protection and use of intellectual property where this will maximise the benefits and enable animal disease research to flourish.

In order for research advances to qualify for intellectual property protection, the legal criteria for patent protection must be fulfilled. This means that, to be patentable, the results of research must describe an invention that is:

- novel, i.e. not described elsewhere before
- non-obvious, i.e. involving a step sufficiently inventive that most people working in that field could not have predicted it
- capable of industrial application, i.e. described in such a way that it can be made or used.

Patents, including those covering genes and their products, are no exception, and STAR-IDAZ IRC is supportive of these if there is sufficient information to indicate that the DNA sequences in question can be used for the benefit of animal health. STAR-IDAZ does not support the patenting



of raw DNA sequences in the absence of such information. This is in line with EU law, which states that a gene sequence, whether partial or complete, is only patentable when it has been isolated and its function described.

STAR-IDAZ IRC is particularly concerned about patents and patent applications that are unreasonably broad and opportunistic, e.g. when there is limited functional data available to support those patent claims. STAR-IDAZ IRC may challenge such speculative patents if it believes that they are being applied for or used in ways that could be detrimental to research or limiting to the development of tools or strategies for the control of animal disease.

### **Policy on intellectual property and patenting**

- STAR-IDAZ IRC supports the appropriate protection and use of intellectual property rights (IPR) to maximise the benefit for the control of animal disease and to enable animal disease research to flourish.
- As such, STAR-IDAZ IRC supports the protection of research findings that meet the legal criteria for the filing of patents, that is, that findings should be novel, non-obvious (i.e. inventive) and capable of industrial application.
- STAR-IDAZ IRC believes that the basic DNA sequence of livestock species and other organisms should be placed in the public domain as soon as is practical, without any fees, patents, licences or limitations on use, giving free and equal access to all. Subject to this, STAR-IDAZ IRC is supportive of patents encompassing genes and their products when there is research data or information indicating that a particular DNA sequence has a utility such that the legal criteria for patenting can be met.
- STAR-IDAZ IRC is concerned about the inappropriate use of patents that it considers to be detrimental to scientific endeavour or to advances in the development of animal disease control tools and strategies.

### **Research Publishing and Open Access**

The main output of research is new ideas and knowledge, which STAR-IDAZ IRC expects its researchers to publish as high-quality, peer-reviewed research articles.

STAR-IDAZ IRC believes that maximising the distribution of these publications - by providing free, online access - is the most effective way of ensuring that the research can be accessed, read and built upon. In turn, this will foster a richer research culture.

STAR-IDAZ IRC therefore supports unrestricted access to the published output of research to be encouraged wherever possible.



Specifically, the STAR-IDAZ IRC:

- expects authors of research papers, monographs and book chapters to maximise the opportunities to make their results available for free
- expects STAR-IDAZ IRC funded researchers to select publishing routes that ensure the work is available immediately on publication in its final published form, wherever such options exist for their publisher of choice and are compliant with our policy
- recommends that, where possible, grant-holders be provided with additional funding to cover open access charges, where appropriate,
- encourages authors and publishers to licence research papers using the Creative Commons Attribution licence (CC-BY) so they may be freely copied and re-used (for example, for text- and data-mining purposes or creating a translation), provided that such uses are fully attributed
- affirms the principle that it is the intrinsic merit of the work, and not the title of the journal or the publisher with which an author's work is published, that should be considered in making funding decisions.

## **Policy and guidelines for funding bodies, Members of STAR-IDAZ IRC**

### ***Policies:***

STAR-IDAZ members will encourage the development of prototype vaccines, diagnostics, therapeutics and disease control strategies that could be approved by 2025, while respecting each funding entity's strategic research agenda.

STAR-IDAZ IRC members will encourage and facilitate rapid data release.

STAR-IDAZ IRC members will disseminate relevant information on their research project portfolio through adequate and timely measures, in particular the STAR-IDAZ IRC website.

### ***Guidelines:***

STAR-IDAZ IRC members should promote collaborative multinational studies, with common study procedures and harmonized policies for regulatory and ethical requirements.

STAR-IDAZ IRC shall publish its mission statement, list of member organizations and list of associated projects. STAR-IDAZ IRC shall publish non-confidential proceedings, as well as the minutes and approved documents of its Executive Committee, the Scientific Committees and the Working Groups.

STAR-IDAZ IRC associated projects and STAR-IDAZ IRC member organizations should make reference to STAR-IDAZ IRC, where appropriate, on organizational websites, information material and presentations.



STAR-IDAZ IRC will promote active exchanges, events and activities between stakeholders, including livestock industry organizations.

Education, training and awareness of stakeholders should be encouraged by STAR-IDAZ IRC.