



STAR-IDAZ
International Research
Consortium on Animal Health

Open data, IP and early engagement with industry



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1. 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 and zoonoses are of a global nature. The STAR-IDAZ International Research Consortium (STAR-IDAZ IRC), a forum of R&D programme owners and managers and international organisations, was established for the purpose of sharing information, coordinating research activities and working towards common research agendas and coordinated research funding on the major animal diseases/infections affecting livestock production and human health.

The mission 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

2. Objectives

The objective of this policy relating to open data, intellectual property and early engagement with industry is to promote knowledge creation together with its disclosure and exploitation to achieve a fair allocation of rights, to reward innovation and to speed up the development of new and improved animal health strategies. It specifically aims to provide a clear statement for IRC-funded scientists relating to the protection and use of intellectual property through patents.

3. Definitions

“Access Rights” shall mean the right to use. Use should in each case be defined under a clear licence¹

“Intellectual Assets” shall mean any results or products of research and development activities of any nature including, but not limited to, knowledge, publications and other information products, databases, technologies, inventions, know-how, processes and software whether or not they are protected by IP rights.

“Background” shall mean data, know-how and information which is held by a participant prior to accession to joint/collaborative activities/ventures with other parties, as well as copyrights and other intellectual and industrial property rights pertaining to such information and which is necessary for carrying out the proposed joint activities.

“Confidential Information” shall mean any and all written information communicated between the parties in collaborative activities clearly identified or marked as being confidential at the moment of its disclosure except for the information which the receiving party can prove (a) is, at the time of communication, in the public domain, (b) after the communication, becomes part of the public domain by publication or otherwise, except by breach of this agreement by the receiving party, (c) is obtained from a third party not in breach of any obligation of confidentiality, (d) is known by the receiving party prior the date of the communication, (e) is required to be disclosed by the receiving party pursuant to any applicable law or judicial or governmental order, provided that the receiving party shall give immediate written notice of such requirement to the disclosing party with the view to agreeing the timing and the content of such disclosure. Whenever Confidential Information is communicated orally, its confidential nature shall be confirmed in writing by the disclosing party within thirty (30) days after such disclosure.

“Direct Exploitation” shall mean to develop for commercialization or to commercialize Foreground itself

“Dissemination” shall mean disclosure by any appropriate means other than that resulting from the formalities for protection, and including the publication in any medium.

“FAIR Data”: data published according to the FAIR Data guiding principles which seek to make data Findable, Accessible, Interoperable, and Re-usable.

“Fair and Reasonable Terms” shall mean appropriate conditions including financial terms (where appropriate) taking into account the actual or potential value of the Foreground or Background to which access is requested and other characteristics of the Research Use envisaged.

“Foreground” shall mean the results, including data, know-how and information, whether or not they can be protected, which are generated under the project and excluding Sideground. Such results include rights related to copyright; design rights; patent rights; or similar forms of protection.

“Open Data”: Open data is data that anyone can access, use or share. It follows the broad principles of the Open Definition.²

“Research Use” shall mean use of Foreground or Background necessary to use Foreground for all purposes other than for completing the project or for Direct Exploitation. (An example of Research Use will be the application of Foreground as a tool for research and clinical research in the discovery, development or commercialisation of pharmaceutical products by for-profit institutions and organisations)

“Sideground” shall mean the results, including data, know-how and information, whether or not they can be protected, which are generated by a Participant under a collaborative project but outside of the project objectives and which are not needed for undertaking and completing the project or the Research Use of Foreground

¹ For open data or open access publications, open source software, etc. one should consider clear use of appropriate open content licenses <http://opendefinition.org/guide/>

² <http://opendefinition.org/od/2.1/en/>

4. Data Sharing Policy, FAIR and Open Data

Generating data is expensive and time-consuming. As funders and programme managers' of this research, we believe that making research data sets available to investigators beyond the original research team in a timely and responsible manner, subject to appropriate safeguards, will generate three key benefits:

- faster progress in improving animal and human health
- better value for money
- higher quality science.

Each organisation will work within its own legal and operational framework, and we are committed to working towards these goals together. We intend to establish joint working groups where appropriate, but consider that data should be shared according to the FAIR Data Principles, being 'as open as possible; as closed as necessary'³. We call on governments and other actors that generate routine animal health data (including statistics) to adopt a similar approach. Institutional and project specific data management policies and plans should be in accordance with relevant standards and community best practice. Data with acknowledged long term value should be preserved and remain accessible and usable for future research.

This following Statement, previously adopted by STAR-IDAZ, establishes guiding principles and desired goals. It recognises that flexibility and a variety of approaches will be needed in order to balance the rights of the individuals and communities that contribute data, the investigators that design research and collect and analyse data, and the wider scientific community that might productively use data for further research.

The joint statement of purpose

Vision

We, as funders of research and/or research programme managers, intend to work together to increase the availability to the scientific community of the research data we fund that is collected for the purpose of animal health and/or zoonoses research, and to promote the efficient use of those data to accelerate improvements in animal and public health.

Principles

Funders and research programme managers agree to promote greater access to and use of data in ways that are:

- *Equitable: Any approach to the sharing of data should recognise and balance the needs of researchers who generate and use data, other analysts who might want to reuse those data, the livestock industries, public health authorities and funders who expect benefits to arise from research.*
- *Efficient: Any approach to data sharing should improve the quality and value of research and increase its contribution to improving animal and public health. Approaches should be proportionate and build on existing practice and reduce unnecessary duplication and competition.*

Goals

While we recognise that progress may be gradual as we develop mechanisms and resources consistent with these principles, we aim to work in concert to achieve the following.

³ <https://www.force11.org/group/fairgroup/fairprinciples>

Immediate goals

- *Data management standards that support data sharing drawing on the FAIR principles*
- *Standards of data management are developed, promoted and entrenched so that research data can be shared routinely, and re-used effectively.*
- *To enable research data to be discoverable and effectively reused by others, sufficient metadata should be recorded and made openly available to enable other researchers to understand the research and re-use potential of the data. Published results should always include information on how to access the supporting data.*
- *Data sharing is recognized as a professional achievement*
- *Funders and employers of researchers recognize data management and sharing of well-managed datasets as an important professional indicator of success in research.*
- *Making research data sets available, in a timely manner, subject to appropriate safeguards*
To ensure that research teams get appropriate recognition for the effort involved in collecting and analysing data, those who undertake research work may be entitled to a limited period of privileged use of the data they have collected to enable them to publish the results of their research.
Making research data sets available according to ethical considerations. All projects to consider potential ethical issues associated with data collection, storage and use. We recommend the use of a Data Ethics Canvas for guiding consideration of management of major data sets likely to be subject to ethical concerns⁴
- *Secondary data users respect the rights of producers and add value to the data they use*
- *Researchers creating data sets for secondary analysis from shared primary data are expected to share those data sets and act with integrity and in line with good practice - giving due acknowledgement to the generators of the original data.*
- *In order to recognise the intellectual contributions of researchers who generate, preserve and share key research datasets, all users of research data should acknowledge the sources of their data and abide by the terms and conditions under which they are accessed*
- *Data collection with intent to open - Data will be collected and documented in such a way that it needs minimal processing to be made open according to the selected standards. Research and experimental design will incorporate data collection with intent to open.*

Longer-term aspirations

- *Well documented data sets are available for secondary analysis*
- *Data collected for animal health research are made available to the scientific community for analysis which adds value to existing knowledge and which leads to improvements in animal health or a reduction in zoonotic threats to human health.*
- *Capacity to manage and analyse data is strengthened*
- *The research community, particularly those collecting data in developing countries, develop the capacity to manage and analyse those data locally, as well as contributing to international analysis efforts.*
- *Published work and data are linked and archived*
- *To the extent possible, datasets underpinning research papers in peer-reviewed journals are archived and made available to other researchers in a clear and transparent manner. Open access publishing with publishing of associated data sets is encouraged.*
- *Data sharing is sustainably resourced for the long term*
- *The human and technical resources and infrastructures needed to support data management, archiving and access are developed and supported for long-term sustainability.*

⁴ <https://theodi.org/the-data-ethics-canvas>

5. Intellectual Property

While research providers funded by the IRC partners will be encouraged to make resources open access, deposit raw data in accessible online repositories and share early results with others it is important for the researcher, the funding bodies and industry that IP is properly protected. STAR-IDAZ IRC supports the appropriate protection and use of intellectual property where this will maximise animal health benefits and enable veterinary research to flourish. It therefore supports the protection of research findings that meet the legal criteria for the filing of patents as essential in creating the best conditions for research and in translating that research into tangible benefits for animal health and the animal health sector. This policy aims to provide a common set of principles to govern the management of intellectual assets (IA) produced, acquired or disseminated by IRC partners and their research providers. It is intended to be supportive of and consistent with:

- The Convention on Biological Diversity and its Nagoya Protocol on Access and Benefit Sharing - and the objectives including the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilisation of genetic resources.
- International agreements promoting the respect for intellectual property and use including the agreement on trade and related aspects of intellectual property rights of the World Trade Organisation; relevant World Intellectual Property Office treaties.

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 to develop animal health benefits. STAR-IDAZ IRC 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 believes that the basic DNA sequence of domesticated animals 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 promotes access to research results to the greatest extent possible so that they may form the basis of future discoveries and lead to public benefit. However, it recognises that intellectual property protection (patents in particular) is a valuable tool to provide incentives for the translation of research results into products that benefit animal health. To achieve its aims, STAR-IDAZ IRC believes that intellectual property issues must be approached carefully in light of individual circumstances.

Where IP arise from their research the IRC encourages researcher providers to consider whether the protection, management and exploitation of such IP is an appropriate means of achieving the benefits for animal health. Potentially patentable research results may require different intellectual property management approaches. For projects that involve production of large-scale datasets, where the outcomes are generally regarded as too early on the research spectrum to have translation potential, an approach that focuses on releasing data as quickly and freely as possible in order to facilitate further research is desirable. In cases where researchers wish to exploit grant-funded IP that does have translation potential, the funding body may agree but recommend particular conditions, such as non-exclusive licensing and reserving rights for research use, to ensure that the patent is exploited to achieve

the aims of the funding body. In certain situations exclusive licensing may be the best way of exploiting research results to achieve public benefit. Some techniques that funding bodies may use include:

- adopting techniques to discourage – and sometimes prevent – patenting of foundational discoveries that could provide greater benefit if their use by the research community remained unrestricted.

In relation to fundamental genome sequences from the human genome project the Bermuda Principles advocated automatic release of sequence assemblies larger than 1KB (preferably within 24 hours), immediate publication of finished annotated sequences, and making the entire sequence freely available in the public domain for both research and development in order to maximise benefits to society. These actions were intended to allow researchers – academic and commercial – to make immediate use of the data while also optimising coordination and independent checking. It was also hoped that early release of the data would lead to the prompt creation of ‘prior art’ that could potentially defeat patent claims based on similar DNA-sequencing efforts in the private sector.

To prevent parties taking action that would restrict access to the data produced by a project where the data when released is incomplete and not considered patentable but it is felt important that it is released quickly into the public domain so as to accelerate the work of others in the area the data can be made available under the terms of a “click wrap” licence.

Material Transfer Agreements can be used where a party wishes to make biological resources freely available to the research community but wishes to protect its own use of the material in the event that anyone should file patents on them. The MTAs may or may not contain reach-through provisions (which give the provider of materials rights to resulting inventions made by the recipient using the materials), but they should contain a non-exclusive royalty-free sub-licensable licence back to the provider of any patents that the recipient files directly on the materials, so that the provider can continue to distribute the materials to third parties.

Material can be made available under appropriate MTA terms including i) the materials or components of the material should be used only in the laboratory that has signed the MTA and will not be distributed to third parties without authorisation of the owners and ii) the recipient agrees not to claim IPR ownership over the materials or components of the materials

- including in certain funding agreements clauses to ensure that patents arising out of the research may be used to advance research, such as:
 - a covenant not to sue or threaten to sue not-for-profit institutions carrying out non-commercial research for infringement of patents
 - the granting or reservation of a research use licence (which may be sub-licensable) to the funding body or relevant institution
- including in grant conditions and funding agreements clauses to ensure that the research is exploited for benefit of animal health, including clauses that relate specifically to the delivery of products to benefit developing country markets; the clauses may include:
 - the right to take over exploitation of the IP if the grantee is not doing so adequately
 - the right to terminate the funding agreement in the event of a change of control (when providing funding to a company) if the change would have an adverse effect on the research or the interests of the funding body
- including in grant conditions and funding agreements clauses to ensure that intellectual property arising from the research is protected (where appropriate), such as:
 - the right for the funder to take action to protect IP if the grantee fails to do so
 - establishment of a dedicated IP management committee to advise on IP strategy.

In the case of more applied research strategic protection of intellectual property should be encouraged to ensure that it can be fully exploited and that sufficient protection is in place to prevent being blocked from further exploitation of the technology.

Limited exclusivity should be considered for commercialisation of intellectual assets where such exclusivity is necessary for the further improvement of such intellectual assets or to enhance the scale or scope of impact on target beneficiaries. It should be limited as possible in duration, territory and or field of use.

5.1 Partnerships and Incorporating Third Party Intellectual Assets

In establishing agreements between collaborators consideration should be given to including IPR provisions that adhere to the following objectives:

- Protect the collaborators own confidential information as required by the collaborators own policies;
- Ensure that access to outputs of such collaboration are made available on a fair and equitable basis with as few restrictions as possible;
- Allow for commercialisation
- Require the collaborator to incur any costs associated with obtaining, maintaining , and commercialising any resulting IPR
- Ensure that all parties to the collaboration obtain a non-exclusive, irrevocable, world-wide, royalty-free right to use any resulting IPR and
- Require the payment to the various parties of royalties based on the net profit of money earned on any resulting IPR

5.1.1 Identification, Ownership and Transfer of IA

a). Background

1. Each Participant shall remain the exclusive owner of its Background.

2. The Background to be included in collaborative project shall be identified in a Collaborative Agreement.

The Participants shall identify in the Collaborative Agreement any legal restrictions which exist relating to the use of such Background for Research Use or for completing the collaborative project, and of which they are aware. The impact of any such restrictions in achieving the project objectives should be considered carefully.

Participants should be entitled but not obliged to introduce into the project and to designate as Background data and information as well as know-how, copyrights or other intellectual property rights pertaining to such information and which is generated or held or acquired by a participant after the initiation of the collaborative activities.

3. Each participant shall remain free to license, assign or otherwise dispose of its ownership rights in Background, subject to any rights and obligations of the Collaborative Agreement.

Where a Participant transfers ownership of Background, it shall pass on its obligations regarding that Background, as defined in the Collaborative Agreement to the assignee including the obligation to pass those obligations on to any subsequent assignee.

Notwithstanding the above, a Participant may - without the permission of the other Participants, but provided that other Participants are informed and that the assignee agrees in writing to be bound by the Collaborative Agreement and this Policy - assign its Background to

(i) its Affiliated Entity; or (ii) any purchaser of all or substantially all of its assets; or (iii) any successor entity resulting from the merger or consolidation of such party with or into such entities.

b). Foreground

1. Ownership of the Foreground belongs in the first instance to the Participant(s) who generated it.

The Participants may agree on a different allocation of ownership in the Collaborative Agreement.

If employees or any party working on behalf of a Participant are entitled to claim rights to Foreground, the Participant shall ensure that it is possible to exercise those rights in a manner compatible with its obligations under the Collaborative Agreement.

2. Where several Participants have jointly carried out work generating Foreground and where no individual Participant can be identified as its owner, such Participants shall, unless otherwise agreed in the Collaborative Agreement, have joint ownership of such Foreground.

In case of joint ownership, unless otherwise agreed in the Collaborative Agreement, each joint owner shall have the right to use such jointly owned Foreground, including the right to grant nonexclusive licenses, with the following conditions:

- Prior notice must be given to the to any other joint owner(s);
- Fair and reasonable compensation must be provided to the other joint owner(s).

3. Each Participant shall remain free to license, assign or otherwise dispose of its ownership rights in

Foreground:

- As expressly permitted in the Collaborative Agreement;
- Or after obtaining the consent of all Participants, which may only be withheld where they can demonstrate that their rights would be adversely affected.

Where a Participant transfers ownership of Foreground, it shall pass on its obligations regarding that Foreground, as defined in the Collaborative Agreements, to the assignee including the obligation to pass those obligations on to any subsequent assignee.

Notwithstanding the above, a Participant may - without the permission of the other Participants but provided that other Participants are informed and that the assignee agrees in writing to be bound by the Collaborative Agreement and this Policy - assign its Foreground to (i) its Affiliated Entity; or (ii) any purchaser of all or substantially all of its assets; or (iii) any successor entity resulting from the merger or consolidation of such party with or into such entities;

c). Sideground

Ownership of the Sideground belongs in the first instance to the Participant(s) who generated it. The Participants may agree on a different allocation of ownership in the Collaborative Agreement.

5.1.2 Access Rights

a). Principles

1. All requests for Access Rights shall be made in writing, unless otherwise agreed in the Collaborative Agreement.
2. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.
3. The termination of the participation of a Participant shall in no way affect the obligation of that Participant to grant Access Rights to the remaining Participants and Third Parties.
4. Unless otherwise agreed by the owner of the Foreground or Background, Access Rights shall confer no entitlement to grant sub-licences. However, any person to whom rights for completing the Project or for Research Use have been made available under this IP Policy may authorise another party to exercise those rights on its behalf providing that that person shall be liable for the acts of that party as if those acts have been performed by this person.

b). Access Rights to the Participants for completing the Project

1. **Foreground.** During the Project, Participants shall enjoy Access Rights to the Foreground of the other Participants solely for the purpose and to the extent necessary for undertaking and completing the Project.

Such Access Rights shall be granted on a royalty-free basis.

2. **Background.** During the Project, The Participants shall, unless prevented or restricted from doing so by obligations to others which exist at the date of accession to the Project Agreement, as identified in III.1(2), enjoy Access Rights to the Background of the other Participants solely for the purpose and to the extent necessary for undertaking and completing the Project.

Such Access Rights shall be granted on a royalty-free basis.

c). Access Rights to the Participants and Affiliated Entities for Research Use

1. **Foreground.** During and after completion of the Project, Participants and their Affiliated Entities shall enjoy Access Rights to the Foreground of the other Participants for Research Use. Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms or royalty-free, as determined in the Project Agreement.

2. **Background.** During and after completion of the Project, Participants and their Affiliated Entities shall enjoy Access Rights to the Background of the other Participants, but only to the extent reasonably required for and only for the purpose of the Research Use of Foreground. Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms or royalty-free, as determined in the Project Agreement.

d). Access Rights to Third Parties for Research Use

1. **Foreground.** After the completion of the Project, Third Parties shall have the right to request and receive under licence Access Rights to the Foreground of the Participants for Research Use. Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms, as determined in the Project Agreement.

2. **Background.** After the completion of the Project, Third Parties shall have the right to request and receive under licence Access Rights to the Background of the Participants, but only to the extent reasonably required for and only for the purpose of the Research Use of Foreground. Such Access Rights shall be granted on a non-exclusive basis under Fair and reasonable terms, as determined in the Project Agreement.

3. The terms for providing Access Rights under paragraphs 1 and 2 shall be included in the Collaborative Agreement.

4. Before execution of the Project, a Participant may identify specific elements of the Background and provide a reasoned request to the owners that such elements shall be wholly or partially excluded from the obligations referred to in this section. Such request may be granted on such conditions as it may agree with the Participant. Any exceptions shall be included in the Collaborative Agreement and cannot be changed unless such change is permitted in the Collaborative Agreement.

e). Access Rights for Direct Exploitation

1. Participants may use, exploit, sublicense or otherwise commercialise their Foreground, Background and Sideground as they see fit beyond the Research Use rights described in this Policy.

2. Where Direct Exploitation by a Participant or Third Party requires Foreground or Background necessary to use Foreground owned by another Participant, the Access Rights will be negotiated between the parties involved as they see fit. Participants may agree on such Access Rights in the Project Agreement.

5.1.3 Confidential Information

1. The Participants covenant not to disclose and not to use the Confidential Information received from other Participants except as provided in and for the purposes of the Collaborative Agreement.

2. Unless otherwise agreed in the Collaborative Agreement, each Participant may disseminate (through journals, lectures, or otherwise) information relating to Foreground, provided that a copy of the proposed dissemination shall have been provided to the other Participants at least thirty (30) days prior to the submission of any written publication or any oral dissemination to allow the Participants to determine whether any invention or Confidential Information would be disclosed. The reviewing Participants shall have the right to (a) require a delay in publication or presentation in order to protect patentable information, (b) require modifications to the publication for patent reasons or (c) require that Confidential Information be maintained as a trade secret. The delay required by the reviewing Participants in publication or presentation in order to protect patentable information shall not exceed three months, unless agreed in the Collaborative Agreement.

5.1.4 Dissemination of Foreground

1. The Participants undertake to disseminate the Foreground (as described in the Project Objective) as soon as reasonably practicable but not later than one (1) year after the termination or expiry of the Project.
2. The Project Agreement shall include a description of the material which must be disseminated in accordance with the IP Policy and referenced in the Grant Agreement.
3. If the Participants do not disseminate within such time periods without good reason, the funding body may have included in the grant agreement the right to disseminate such results in a manner consistent with the grant agreement.

6. Early Engagement with Industry

Partnerships, including with product development partners, are usually critical to harnessing efficiencies in product development and achieving maximum impact through effective delivery and deployment.

STAR-IDAZ IRC aims to bring together researchers, and Industry (and investors) to help ensure that promising lines of research yield practical benefits for animal health. In realising the potential benefit of research outputs at the earliest possible opportunity it is essential that the researchers engage with industry partners so that the research is conducted under experimental conditions that the data generated can contribute to product registration and not just provide proof-of-concept. All such partnerships should be governed by appropriate governing agreements including confidentiality and material transfer agreements to clearly define access to and use of information and materials between the parties concerned.

