VETBIONET

Veterinary Biocontained facility Network for excellence in animal infectiology research and experimentation

Deliverable D6.3

Draft plan outlining strategies for VetBioNet sustainability

Consolidated with Deliverable 6.2

Draft prototype of structure and mode of operation for the future of VetBioNet

Due date of deliverable: M44

Actual submission date: M72

Start date of the project: March 1st, 2017 **Duration:** 72 months

Organisation name of lead contractor: MRI

Revision: V3

Dissemination level	
Public	**PU**
Confidential, only for members of the consortium (including Commission Services)	
Classified, as referred to in Commission Decision 2001/844/EC	

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1. Summary

Objectives:

D6.2 and D6.3 relate to Task 6.2 (*Definition of a Sustainability Plan for the future of VetBioNet*) within WP6 (*Network Sustainability*). The principal objectives of Task 6.2 are to develop a structure and strategic plan for network sustainability which maintains those priority areas identified from the initial sustainability workshop beyond the current term of funding under Horizon 2020.

Rationale:

A Sustainability Board comprising five VetBioNet partners (MRI, INRAE, AU, WBVR, FLI) was established to provide leadership on matters relating to network sustainability. The members of the Sustainability Board were instrumental in delivering the first Stakeholder Workshop (Brussels, Nov 2017) and in the discussions relating to the development of the prototype structure for VetBioNet sustainability described below.

Teams involved:

This activity involved the VetBioNet Sustainability Board members from MRI, INRAE, AU, WBVR and FLI with additional support from UNNOT.

2. Introduction

The aim of these deliverables is to develop a structure and strategic plan for network sustainability, which progresses from the outputs of Deliverable 6.1 which identified those activities and tools the network partners identified to be maintained after the current period of VetBioNet funding ends. These priority areas include:

i. transnational access to the BSL3 facilities and the specialised expertise within the facilities;
ii. finding mechanisms for exchange of valuable samples;
iii. provision of guidelines on ethics and best practice;
iv. access to experimental protocols and new technologies that reduce animal usage (3Rs);
v. establishing mechanisms for data access and data sharing (including data protection and confidentiality) via an outward-facing web portal for the network.

Progress with deliverables 6.2 and 6.3 was achieved through input from the Stakeholder Advisory Board (SAB), consultation between members of the sustainability board and through

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discussions involving consortium members at annual project and Executive Committee meetings between 2019 and 2023.

These meetings aimed to:

i. agree on the appointment of a new WP6 (Network sustainability) leader following the departure of the work package leader in 2019;
ii. agree on the areas of the VetBioNet project that are essential components of a future infrastructure network;
iii. explore the range of options available for sustainability of the VetBioNet project and agree on a strategy to move this forward;
iv. explore options to sustain tools and resources developed by VetBioNet;
v. decide on a date and venue for the final Stakeholder meeting at which the sustainability route will be presented to consortium partners, stakeholders and SAB members.

Additional teleconference meetings of the Sustainability Board and the VetBioNet Executive Committee (ExCom) addressing D6.2 and D6.3 were used to prepare the VetBioNet mid-term review report, the review response letter, the periodic M36 project report and integrate the Project Officer's and the reviewer's feedback on the future role of VetBioNet in the European response to emerging infectious disease outbreaks.

Within a funding environment where long-term sustainability of research and research infrastructures at individual and collective levels is already challenging, the ExCom members agreed that VetBioNet "sustainability" is critically dependent on sustained research and networking activities and that a future infrastructure project must not only rest on providing services (TNA) but should also include Joint Research Activities (JRA) and Networking Activities (NA). Importantly, these integrating activities must be tailored to address key global policy areas such as: (i) the coordination of the European research response to emerging disease threats; (ii) the impact of global warming on epizootic and/or zoonotic disease spread; (iii) the role of livestock and wildlife species as spill-over hosts for zoonotic disease spread; (iv) the societal impact of emerging infectious disease outbreaks; and (v) the harmonisation of biosecurity protocols.

To improve and update the services VetBioNet is offering, it is essential that the partners continue to seek funding that supports Joint Research Activities. As an evolution from the present project, these activities may include: (i) development or validation of reservoir host models; (ii) development and validation of animal models for vaccine-challenge trials; (iii) development and validation of animal infection models for vector-transmitted diseases; (iv)

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development of novel tools to assess pathogen transmission and pathogenesis in farm animals and wildlife species; (v) development of alternative spill-over host infection models and (vi) development of new research tools that enhance the outputs from infectious disease studies in livestock species.

Through discussions involving the Sustainability Board, Executive Committee and consortium members, it was agreed that a sustainable structure would always be likely to require funding from individual member countries and/or the EU Commission as:

- The costs of operating sophisticated high-level biocontainment facilities and of carrying out studies with BSL3/BSL4 pathogens are extremely high.
- For even large commercial companies, studies involving BSL3/4 pathogens are high risk and commercialization opportunities limited.
- Many studies of pathogens that require high containment are academic fundamental research in nature with limited immediate economic benefit.

3. Results

i. Agree on the appointment of a new WP6 (Network sustainability) lead

Following the departure of the previous work package leader, it was agreed by the project coordinator, Executive Committee and the Sustainability Board that Dr Keith Ballingall (MRI) would take over the lead for WP6.

ii. Agree on the components of the VetBioNet project that are key to the success of a future infrastructure network

From the list of components identified in the first sustainability workshop and listed above, access to large animal BSL3 facilities and the specialised expertise within these facilities across Europe was identified as the key component for inclusion in a future infrastructure network. Other activities provide support key to the efficient operation of large animal infectious disease infrastructures including research activities which provide new tools, technologies and reagents, the continued development of best practice, to the ethics and application of the 3R's principals in animal research. All are key to the structure of a future Research Infrastructure (RI) in the field of animal infectious diseases.

iii. Explore the range of options available for sustainability of the VetBioNet project and agree on a strategy to move this forward

Options discussed for project sustainability include;

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i. A European Strategic Framework for Research Infrastructures (ESFRI) application to encompass many or all of the key areas identified in the first sustainability workshop. However, ESFRI applications require support from participating Government Agencies at ministerial level and the Sustainability Board considered it unlikely that a minimum of three individual governments (required for an ESFRI application) would guarantee support for such an infrastructure entity when significant support was already provided to fund national high containment infrastructures. Although in some countries (France and The Netherlands), experimental facilities for infectious disease research have been registered in the national infrastructure roadmap, the respective research organizations and governments have stipulated other priorities for the near future. In addition, the impact of Brexit has yet to be resolved and with five partners of VetBioNet from the UK (APHA, TPI, UNNOT, MRI and UEDIN) their ability to contribute to an ESFRI application or future Horizon Europe projects remains unclear. Input from meetings with the Stakeholder Advisory Board (videoconferences and annual project meetings) indicated that an ESFRI application would require a prompt consortium decision on the network priorities and core partners and a (re-)focus on selected VetBioNet services and activities. The sustainability board felt that, at the present stage of the project, it would be too early to come to vital conclusions concerning the core partners and integrating activities of VetBioNet as an ESFRI.

ii. The second option considered was to seek support for the funding of a new infrastructure project, which builds on the successes of VetBioNet. This would require a targeted INFRA call within the “Horizon Europe” programme. While this was the preferred and arguably easy option of the sustainability board, it is now apparent through the project officer’s comments on earlier drafts of this document that striving for support for a VetBioNet-like project in its current form under Horizon Europe cannot be seen as a durable sustainability strategy. Still, it should be underscored that parts of the VetBioNet activities, i.e. research services (Transnational Access) in the field of zoonotic infectious diseases, are today an integral part of the ISIDORe project (HORIZON-INFRA-2021-EMERGENCY-02 call, see point iv below). Other HE infrastructure project calls (e.g. INFRA-SERV, INFRA-TECH) may provide additional funding opportunities to maintain or expand the network’s research services and joint research activities.

iii. While some core support for the infrastructure network through Horizon Europe may be available, additional complementary sources of funding would be sought through closer links with the animal and public health industry. This may include sponsorship from industrial partners of online resources developed through

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VetBioNet to include company logos and adverts for products. Funding from the animal and public health industry could be sought for workshops, training courses, studentships, and industrial partnerships.

iv. The possibility of follow-up funding by Horizon Europe notwithstanding, the Sustainability Board also discussed additional and/or concurrent options to sustain the primary VetBioNet activities. Asked by the EC to explore the possibility of joining forces in a consolidated European Research Infrastructure, the coordinators of VetBioNet and four other EU RIs operating in the field of infectious diseases (Infravec, TRANSVAC, EVAg and ERINHA) have deliberated on this matter and developed a consultation paper on the creation of a "European Epidemic Disease Research Infrastructure" (EDRI). This consultation paper (sent to the EC in June 2020) has informed the HORIZON-INFRA-2021-EMERGENCY-02 call (Research infrastructure services for rapid research responses to COVID-19 and other infectious disease epidemics) and paved the way for the ISIDORe (Integrated Services for Infectious Disease Outbreak Research) project (21M€, 2022-25). Under the umbrella of 17 European life sciences research infrastructures or networks (including VetBioNet), ISIDORe brings together 154 partner organisations (including 15 VetBioNet partners), providing services to advance research on epidemic-prone infectious diseases. VetBioNet, represented by INRAE, has a key role in this project by (co)-leading the "ISIDORe Sustainability" work package and two service work packages (WP11 "Ex-Vivo Models", WP14 "In-Vivo Models"). WP11 "Ex-Vivo Models" and WP14 "In-Vivo Models" services are on high demand in the ISIDORe project, and the VetBioNet service providers offer the largest and most diverse service portfolio in these two work packages. ISIDORe maintains parts of the VetBioNet activities by offering Transnational Access to the network's infrastructure capacities; however, it focuses on human epidemic-prone human infectious diseases (including zoonotic diseases) rather than veterinary infectious diseases. Importantly, the RI linkages and coordinated activities outlined in the EDRI consultation paper, and partially implemented in the ISIDORe project, could provide a future-proof framework for the structure and development of VetBioNet over the next decade.

v. In parallel to the preparation of the ISIDORe project, VetBioNet has engaged in discussions with the coordinators of the candidate European Partnership Animal Health & Welfare (EUP AH&W) to explore the possibility of VetBioNet participating in the partnership. The EUP AH&W intends to be a Research and Innovation Partnership set up in the context of Horizon Europe. Its general goals are to progress Europe towards healthy and sustainable livestock production systems (for

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both terrestrial and aquatic animals), including the reduction of anti-microbial usage, and to greatly improve production animal welfare, in line with the European Green Deal and farm-to-fork strategy. Furthermore, the EUP AH&W will enhance public health and well-being by facilitating cross-sector collaboration in a One Health – One Welfare perspective. Discussions with the EUP AH&W led to the conclusion that VetBioNet is offering capacities and competencies that can help achieving the partnership's objectives, including the sharing of infrastructures (e.g. animal facilities or laboratories of BSL2 or higher). Because of the partnership's co-fund model, and without having a legal status, VetBioNet cannot join the EUP AH&W as a network –only as the sum of the network's partners joining the partnership as Research Performing Organisations. However, the EUP AH&W considers VetBioNet as a key stakeholder that may directly contribute to the partnership by offering unique infrastructure capacities, e.g. access to (high-) containment facilities for terrestrial and aquatic animals. VetBioNet is recognised as a collaborating entity that has contributed to the draft of the Strategic Research and Innovation Agenda (SRIA) for the EUP AH&W.

vi. A key aspect of VetBioNet's involvement in ISIDORe is that it is formally recognized as an infrastructure network represented by INRAE (the VetBioNet project coordinator). As VetBioNet funding comes to an end in February 2023 the Sustainability Board, ExCom and network partners agreed to form a European Research Group (ERG) to maintain key aspects of the network. An ERG is a co-operation instrument formed between parties and tailor made by its members. There is no requirement for a financial contribution for the creation of the ERG. An ERG can operate with in-kind contributions and seconded staff from its members. The formation of VetBioNet-ERG will:

- allow VetBioNet to respond with an existing network to multi-partner funding applications in a manner similar to ISIDORe and the proposed PAHW
- maintain VetBioNet resources, databases and website and facilitate contacts and exchanges of researchers
- Sustain collaborative activities such as exchanging key reagents, methods and staff.
- ensure harmonisation and complementarity through coordinating meetings, conferences and workshops devoted to themes relevant to the ERG.

The development of a VetBioNet-ERG is well-advanced. The ERG agreement document is included in ANNEX 1. This document has been shared between partners, the SAB and

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presented to stakeholders at the Sustainability Workshop at the final network meeting in February 2023.

Development of a strategy to mitigate the effects of Brexit

The consequences of Brexit for the sustainability of VetBioNet have yet to be fully evaluated. Within VetBioNet five partners (APHA, TPI, UNOTT, MRI and UEDIN) are from the UK, including four work package leads. While not essential for the success of a future infrastructure project, the lack of UK participation would significantly alter the network's profile. UK partners continue to value participation in such a network and have committed time and resources to ensure its success. It is hoped that arrangements between the European Commission (EC) and the UK Government are in place to ensure UK based partners' participation in not just a future VetBioNet-like RI but in all other aspects of Horizon Europe. The final arrangements between the EC and the UK Government will not be decided before the end of the current funding for VetBioNet.

VetBioNet Sustainability Workshop during the final project meeting

Important in the process of developing a sustainability plan is to obtain stakeholder feedback. The second stakeholder meeting was planned to take place alongside the annual meeting in May 2020 (WBVR, Lelystad, NL). However, constraints imposed by the COVID-19 pandemic and the subsequent dynamic nature of the discussions for the ISIDORe project and the EUP AH&W necessitated postponing it until the final meeting in February 2023. The meeting was ultimately held as a 1-day workshop (VetBioNet Sustainability Workshop) centred on the sustainability of VetBioNet and other European research infrastructures or networks in the field of infectious diseases or animal health. Stakeholders participating in the workshop included representatives of ERINHA/ISIDORe, TRANSVAC, EVAg, Infravec, EATRIS, AQUAEXCEL and the EUP AH&W (representatives of SmartCow and PIGWEB were invited but not available to participate in the workshop). A video record of the workshop presentations and discussions is available on the VetBioNet website. The workshop minutes are reported in Deliverable D5.10 (public). From the discussions it was concluded that the creation of an ERG will allow VetBioNet to maintain the key elements of its networking activities, and that this sustainability option will certainly help to identify or create new funding opportunities. However, to truly become sustainable, VetBioNet should consider two options for the short- to mid-term: transforming the network into a legal entity or joining another permanent research infrastructure.

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4. Conclusions

The first Stakeholder Workshop identified those activities to be maintained beyond the current term of funding for VetBioNet under Horizon 2020. The identification of mechanisms by which VetBioNet sustainability can be achieved was discussed extensively by the Sustainability Board, ExCom and network partners between 2019 and 2023. These discussions evaluated the pros and cons of an ESFRI Roadmap application, the development of a permanent RI with legal personality, and concluded that maintaining activities such as Transnational Access at any stage of the ESFRI lifecycle would not be compatible with the financial support required from the partners' national Governments. Most importantly, it became evident that continuous joint research activities and networking activities should be an integral part of a future VetBioNet RI or network. Once it was clear that obtaining funding for a VetBioNet-like infrastructure project under Horizon Europe is not a realistic option, the Sustainability Board decided to develop a VetBioNet-ERG to pursue the project's networking activities and to allow VetBioNet to participate as an existing network in multi-partner projects or funding applications , similar to what is done in the ISIDORe project and what is planned for the EUP AH&W. The aims, structure, and mode of operation of the VetBioNet-ERG are set out in ANNEX 1. Alongside the development of a VetBioNet-ERG, VetBioNet will now explore different options for becoming a legal entity (nonprofit organization) so as to facilitate coordinated network activities in future project applications. The possibility of developing partnerships with other European RIs addressing infectious diseases was discussed and has ultimately led to the draft of a concept paper on the creation of a "European Epidemic Disease Research Infrastructure" (EDRI) cluster comprising VetBioNet, Infravec, TRANSVAC, EVAg and ERINHA (ANNEX 2). This consultation paper was instrumental for the development of the ISIDORe project and may serve as blueprint for the preparation of additional joint funding proposals or other concerted actions. Further, in line with the concept of coordinating and synergising the activities of these European RIs or networks, ERINHA and VetBioNet have formalised their cooperation by signing a Memorandum of Understanding (ANNEX 3).

ANNEX 1

VetBioNet ERG

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AGREEMENT ON THE CREATION OF

A EUROPEAN RESEARCH GROUP (ERG)

“VETBIONET”

Between

The National Institute for Agricultural Research, Food and Environment (INSTITUT NATIONAL DE RECHERCHE POUR L'AGRICULTURE, L'ALIMENTATION ET L'ENVIRONNEMENT)
Hereinafter referred to as: **INRAE**
Whose registered office is at: 147 rue de l'Université - 75338 PARIS CEDEX 07
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Hereinafter referred to as "**Coordinator**"

And

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And

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or Jordy de la Cuesta Fernandez, Chief Financial Officer ? (VetBioNet CA)

And

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And

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And

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And

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And

Inmunología y Genética Aplicada, S.A. – SME

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And

Sciensano

And

AGES

Hereafter referred to as « the Parties »

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CONSIDERING

The decisions taken by VetBioNet members during General Assembly meetings of May 2019, December 2020, November 2022 and the final meeting in February 2023, to promote research in veterinary infectious disease within a framework of One Health in the national and European research landscape using research infrastructure ressources from the VetBioNet network, to create a European Research Group (VetBioNet-ERG) in 2023.

HEREBY AGREE:

ARTICLE 1 – CREATION AND DURATION

A European Research Group, co-operation instrument devoid of any legal personality, hereafter referred to as ERG, entitled "**VetBioNet-ERG**" is hereby formed among the Parties, for a period of four (4) years starting February 28th, 2023.

The Agreement can be renewed by addendum. Renewal will be decided by the prior agreement of the Parties in consultation with the General Assembly.

ARTICLE 2 – MISSION

The **VetBioNet-ERG**'s mission shall be to seek support for research and extension in the areas set out in Annex 1.

To fulfil its mission, the Parties through the ERG shall attempt to:

1. Implement the plan for the long-term VetBioNet sustainability;
2. Be a platform for launching further European and international collaborative projects on animal infectious disease research requiring containment facilities;
3. Enlarge the international visibility of the VetBioNet Network of research infrastructures as a European centre of excellence in animal infectious disease research;
4. Promote the One-Health concept and veterinary infectious disease research in national and European research landscapes;
5. Reach out to other stakeholders in order to develop new initiatives and join other programs
    - Promote research priorities identified by the network toward policy makers.
    - Coordinate national actions in accordance with VetBioNet research agenda;
    - Maintain links with Partners from outside Europe;
6. Maintain research capacities and tools developed by VetBioNet for the research community:
    - Ensure continued coordinated interactions among network members.
    - Maintain and expand the mapping of terrestrial and aquatic containment facilities and ressources for veterinary infectious disease research in Europe.
    - Facilitate access to the VetBioNet Network research infrastructures and services and provide information on funding opportunities for projects in animal infectious disease research;
    - Maintain common research tools, associated platforms and databases for joint research projects and share them with the community;
    - Identify funding pathways to develop new tools in support of animal infectious disease research;
    - Continue to provide access to common research methods, standards, protocols and guidelines for biocontained animal experimentation, ethics in animal experimentation and 3Rs (Replacement, Reduction & Refinement) that were produced by VetBioNet and make available best practice guidelines in these areas for the community;
    - Support the development of skills and expertise of researchers through workshops, training courses, short-term missions, mobility exchanges and internships.
7. Bring support to VetBioNet stakeholders by maintaining and updating the dissemination tools developed by VetBioNet including website and data bases.

For the avoidance of doubt and in accordance with Article 6, if some or all Parties wish to participate in any collaborative research projects arising from the ERG, the participating Parties shall enter into and sign a specific contract between/among such Parties in relation to that project.

ARTICLE 3 – MEMBERSHIP

The "**VetBioNet-ERG"** is composed of the Parties as represented by their respective participating laboratories, research departments or centres.

For:

- INRAE - Institut National de Recherche pour l'Agriculture, l'Alimentation et l'Environnement
- WBVR - Stichting Wageningen Research
- FLI - Friedrich Loeffler Institut – Bundesforschungsinstitut Fuer Tiergesundheit
- TPI - The Pirbright Institute LGB
- APHA - Animal and Plant Heath Agency
- MRI - Moredun Research Institute
- INIA - Instituto Nacional De Investigacion Y Tecnologia Agraria Y Alimentaria
- IRTA - Institut de Recerca I Tecnologia Agroalimentaries
- EDI-IVI - Institute Of Virology And Immunology
- PIWET - Panstwowy Instytut Weterynaryjny – Panstwowy Instytut Badawczy
- AU- Aarhus University
- ANSES - Agence Nationale de Securité Sanitaire de l'Alimentation, de l'Environnement et du Travail
- UEDIN - Roslin Institute – University Of Edinburg
- EMC - Erasmus Universitair Medisch Centrum Rotterdam
- IZSVe - Istituto Zooprofilattico Sperimentale Delle Venezie
- UNOTT - The University Of Nottingham
- NUID-UCD - University College Dublin, National University Of Ireland, Dublin
- ILRI - International Livestock Research Institute
- CSIRO - Commonwealth Scientific And Industrial Research Organisation
- EAAP - Federazione Europea di Zootecnica
- ISX - InSCREENex GMBH
- LEICA
- Noldus - Noldus Information Technology BV
- EpiBio - Epibiosafe LTD
- VAL - Vertebrate Antibodies Limited
- INGENASA - Immunologia Y Genetica Aplicada SA
- Canadian Food Inspection Agency
- Department of Homeland Security Science and Technology Directorate
- Sciensano
- AGES

The terms of this Agreement shall only apply to animal infectious disease research in research infrastructures from the VetBioNet network within the above-mentioned Parties.

New members can join the **VetBioNet-ERG** upon the unanimous decision of the Parties and signature by the new member of an addendum to the Agreement.

PROVIDED ALWAYS THAT, the Parties have agreed to the joining of the new member, the **Parties** may mandate the institution of the **VetBioNet-ERG** Coordinator for the signature of this addendum, thus avoiding the complex procedure of a signature by all the Parties.

All staff members taking part in the **VetBioNet-ERG** activities shall continue to be employed by their respective laboratories, research departments or centres, institutions or universities.

ARTICLE 4 – ORGANISATION

4.1 – Co-ordinator

The ERG Coordinator, whose identity is set out in Annex 3, shall be appointed by the Parties for a period of two (2) years, unless otherwise agreed between the Parties.

The Coordinator shall have responsibility for coordinating the ERG activities and providing an annual scientific report, which shall be forwarded to the Parties.

4.2 – General Assembly

The Parties shall set up a General Assembly to coordinate the ERG scientific programme. The General Assembly shall be composed of one representative from each Party. The General Assembly shall be chaired by the Coordinator. It is the final decision-making body of the ERG.

The list of the designated representative from each Party on the General Assembly shall be updated every year by the Executive Committee.

The General Assembly shall:

- Discuss the focus of the ERG's activities and ascertain the current status thereof;
- Express an opinion as to the scientific programme of the ERG, established by the Coordinator and the Executive Committee, and as to the current status of work in progress. It shall suggest new orientations, should it be needed;
- Decide whether to include new members to the VetBioNet-ERG;
- Suggest any modification to the Agreement.

The General Assembly shall convene when and as needed, and at least once a year. It shall convene when the Coordinator and/or at least one-third of its members requests such a meeting. An agenda for each meeting shall be sent by the Coordinator to all Parties at least 21 calendar days before the meeting. Any Party may add an item to the original agenda by written notification to all other Parties no later than 7 calendar days preceding the meeting.

Where necessary, the General Assembly may request the presence of any expert for consultative purposes.

Decisions shall be taken with a qualified majority of three-quarters of the Parties which are present or represented except for the integration of a new Party in the VetBioNet-ERG, which shall require a unanimous decision.

Minutes of the General Assembly meetings, drawn up for each meeting, shall be sent to the Parties for approval.

When necessary, the Coordinator can require that the General Assembly takes a decision by remote electronic vote. The Coordinator will, under these circumstances send an e-mail to all the representatives of the Parties asking for a response within a minimum of 10 working days and a maximum of 15 working days. This may be the case for the integration of a new member in the VetBioNet-ERG.

Decision shall then be taken with a qualified majority of three-quarters of the Parties who answered within the required period, except for the integration of a new Party in the VetBioNet-ERG, which shall require a unanimous decision.

4.3 – Executive Committee

The Parties shall set up an Executive Committee to ensure that the strategy adopted for the ERG is preserved and that the actions required are well implemented. The aforementioned Committee shall be comprised of Task Leaders of the Working Groups of the ERG (see Annex 3). The Executive Committee shall be moderated by the Coordinator.

The Executive Committee shall:

- Propose revisions of the scientific programme of the ERG in collaboration with the Coordinator, and as to the current status of work in progress;
- Discuss and propose the scientific position and strategic actions of the ERG to be validated by the General Assembly;
- Draft yearly ERG scientific reports, which shall be forwarded to the Parties for validation by the General Assembly;
- Propose new laboratories, research departments or centres to be included in the VetBioNet-ERG (submitted to validation by the General Assembly);
- Propose new tasks or working groups if needed (submitted to validation by the General Assembly);
- Suggest any modification to the Agreement.

The Executive Committee shall meet twice annually by video conference at the request of the Coordinator or of one-quarter of its members.

Where necessary, the Executive Committee may request the presence of any expert for consultative purposes.

Decisions shall be taken with a qualified majority of three-quarters of the Task Leaders which are present or represented. Minutes of the Executive Committee meetings, drawn up for each meeting, shall be sent to the Parties.

The Executive Committee shall function as the main link to other Parties, the scientific community and their affiliated networks.

ARTICLE 5 – FINANCIAL PROVISIONS

All activities and tasks associated with the maintenance of the VetBioNet-ERG will involve in-kind contributions from participating organisations. No direct financial contribution is requested from partners. The Coordinator and Executive Committee reserve the right to propose administrative fees to member organisations. This would require majority support from the General Assembly.

For the purposes of drafting the ERG's annual report, at the end of every fiscal year, the Parties shall forward a statement of any ERG-related spending to the Co-ordinator.

ARTICLE 6 – PROJECT PARTICIPATION

Some or all Parties may wish to participate in projects or funding applications coordinated or facilitated by the VetBioNet-ERG. In such cases, interested Parties will will define, specific tasks and responsibilities as well as any financial participation, and any funders' conditions.

ARTICLE 7 – INTELLECTUAL PROPERTY RIGHTS

VetBioNet-ERG is not suited to be a sponsor of research activities so is unlikely to generate intellectual property. Any intellectual property arising from work carried out by a Party prior to the ERG's creation remains the property of that Party. If in the event of intellectual property arising as a result of VetBioNet-ERG activities, the interested parties will seek IP protection through their participating partner organisations.

7.1 – Publications

Any information arising from work carried out by a Party prior to the ERG's creation remains the property of that Party. Any publications resulting from joint ERG efforts shall specify any and all existing links between the ERG Parties involved. This shall include the following statement: "Research carried out under the auspices of **VetBioNet**-ERG".

7.2 – Confidentiality

For the duration of this Agreement and for a further three (3) years thereafter, each Party shall not disclose to third Parties any information obtained through a Party in the ERG and deemed confidential by that Party, without that Party's written agreement save where required to be disclosed to any governmental or other authority or otherwise legally required to be disclosed.

All information in whatever form or mode of transmission, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the ERG during its implementation and which has been explicitly marked as "confidential", or when disclosed orally, has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 30 days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

The Recipients hereby undertake in addition and without prejudice to any commitment of nondisclosure under the ERG, for a period of 3 years after the end of the ERG:

a) not to use Confidential Information otherwise than for the purpose for which it was disclosed;
b) not to disclose Confidential Information to any third party without the prior written consent by the Disclosing Party;
c) to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
d) to return to the Disclosing Party on demand all Confidential Information which has been supplied to or acquired by the Recipients including all copies thereof and to delete all information stored in a machine readable form. If needed for the recording of ongoing obligations, the Recipients may however request to keep a copy for archival purposes only.

The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees and shall ensure that their employees remain so obliged, as far as legally possible, during and after the end of the ERG.

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

a) the Confidential Information becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
b) the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;

c) the Confidential Information is communicated to the Recipient without any obligation of confidence by a third party who is in lawful possession thereof and under no obligation of confidence to the Disclosing Party;
d) the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party; or
e) the Confidential Information was already known to the Recipient prior to disclosure.

The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the ERG as with its own confidential and/or proprietary information, but in no case less than reasonable care.

If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

a) notify the Disclosing Party, and
b) comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

7.3 – Property and exploitation of results

With the exception of the knowledge listed in Annex 2, each Party remains the sole owner of the knowledge, whether or not protected by intellectual property rights or associated rights, held prior to the Agreement or acquired in parallel with it. The Agreement shall not give any right over the aforementioned knowledge to the other Parties.

Results from the ERG shall mean the knowledge arising from any ERG project whether or not it may be protected by intellectual property rights.

Each Party shall have a royalty-free access right, which cannot be sub-licensed, to use the Results for its own internal, non-commercial research work on any ERG Project.

7.3.1 – Protection of knowledge

The Results shall be owned by the Party which generated it. Where Results have been generated by more than one Party ("Joint Results"), they shall be owned by the Parties jointly, each Party being allocated an ownership commensurate with their contribution thereto.

The Party responsible for generation of the Results shall make all decisions on whether and/or how such Results should be protected by patent or other intellectual property protection. The costs of filing and protection of such patent application(s) or other protection shall be paid by the Party generating such Results. In the case of Joint Results, any application for intellectual property rights or associated rights resulting from work carried out within the ERG framework shall be filed in co-ownership, in the joint name and to the joint benefit of the Parties of the inventors, unless one or more joint owners refrains from filing and protection. In such case the remaining owner/owners shall be free to go on with the protection in their sole name and to their sole benefit and the Party/Parties refraining from protection shall assist in this within reason. The Parties shall discuss any such protection that should be sought and use all reasonable endeavours to reach agreement in relation thereto.

In the case of Joint Patents, each Party shall share the costs of filing an application, of the award procedure, of maintaining and of extending the patents or other rights in proportion of their respective contributions, unless otherwise agreed.

The name(s) of the inventor(s) shall be mentioned in applications for patents of other rights' applications.

7.3.2 – Software

Each Party shall remain the sole owner of any software developed solely by that Party before the Agreement and/or outside of its scope.

Jointly developed software is the Joint ownership of the Parties generating it. The same is true for jointly developed extensions as well, whichever the owner of the previous software is. 'Extension' means a software enabling to achieve new functions and performances in comparison with the previous software from which it is released ('Extension' is broader than upgrade).

7.3.3 – Results excluding patents and software

The Parties to the particular ERG project concerned shall be deemed to be joint owners of the rights on databases, either on their structure or on their content, created within the ERG.

7.3.4 – Exploitation of Results

In the event of an industrial or commercial use of the Joint Results from the ERG, the Parties concerned shall decide, in a separate written agreement, on the way of exploiting said Joint Results and of sharing the royalties.

Notwithstanding this Agreement's duration and termination or the withdrawal or exclusion of one of the Parties, the specific contract entered into between the interested Parties under article 6 shall remain in effect.

ARTICLE 8 – MISCELLANEOUS PROVISIONS

8.1 – Inclusion

The entry of a new Party to this Agreement must be by an addendum to this Agreement following the unanimous approval of the Parties.

8.2 – Withdrawal

Any Party may elect to withdraw from the ERG, with three (3) months after prior notice given to the other Parties.

8.3 – Exclusion

Should a Party not fulfill its obligations under this Agreement, the General Assembly may exclude it from the ERG.

To do so, the General Assembly decision shall be unanimously voted by the present members, the representative(s) of the aforementioned Party being excluded from said vote. The quorum for such a vote to take place is three-quarters of all General Assembly members.

8.4 – Termination

In exceptional and justified circumstances, the ERG and this Agreement may be terminated before term by the unanimous agreement of all the Parties, with six (6) months prior notice. In the event of this happening, the Parties undertake to try to complete the joint activities which have already been started.

Termination decisions shall be taken only after an opinion has been expressed on this matter by the competent authorities of the Parties and by the General Assembly.

8.5 – Consequences of Termination

In the event of termination or expiry of this Agreement (whether in relation to all Parties or an individual Party):

i. the provisions of Article 7 shall remain in place;

ii. such termination or expiry shall be without prejudice to any rights or remedies that any Party may have under this Agreement and will not affect the accrued rights or liabilities of any Party.

8.6 – Disputes

In the event of any dispute arising from the interpretation or the implementation of this Agreement, the Parties undertake to settle their dispute amicably.

If it is ultimately impossible to come to a friendly settlement, the claimant Party shall request that the dispute be settled by Arbitration Court, under the Rules of the International Chamber of Commerce (ICC).

The place of arbitration shall be Brussels if not otherwise agreed by the conflicting Parties.

The award of the arbitration will be final and binding upon the Parties.

Nothing in this Agreement shall limit the Parties' right to seek injunctive relief or to enforce an arbitration award in any application in any competent court of law.

8.7 – No Representation

The Parties shall not be entitled to act or make legally binding declarations on behalf of any other Party.

8.8 – Applicable Law

This agreement shall be construed in accordance with and governed by the laws of Belgium.

8.9 – Mandatory national law

Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

FOR

Institut National de la Recherche pour l'Agriculture, l'Alimentation et l'Environnement (INRAE)

Monsieur Marc Guérin, President du centre INRAe du Val de Loire
Date:

Signature:

Stamp of organisation:

FOR

Aarhus University (AU)

Anette Poulsen Miltoft
Division Manager, AU Research Support and External Relations, Technology Transfer Office

Date:

Signature:

Stamp of organisation:

FOR

INSTITUT DE RECERCA I TECNOLOGIES AGROALIMENTARIES (IRTA)

M. Simó Alegre Castellví

Date:

Signature:

Stamp of organisation:

FOR

Federazione Europea di Zootecnica (EAAP)

M. Andrea Rosati
Secretary General

Date:

Signature:

Stamp of organisation:

ANNEX 1

AREAS COVERED BY THE ERG

The **VetBioNet**-ERG will support research on veterinay infectious diseases by maintaining the network of research infrastructures and expertise in One-Health, developed by the VetBioNet project (EU Horizon 2020, 2017-23, Grant Agreement No 731014).

The principal aim of VetBioNet is to establish and maintain a comprehensive network of pre-eminent high-containment research facilities, academic institutes, international organisations and industry partners that is dedicated to advance research on epizootic and zoonotic diseases and to promote technological developments.

VetBioNet includes 3 types of integrating activities:

1. **Transnational Access Activities (TNA)**, consisting mainly in providing free-of-charge access to the BSL3 facilities and technical resources of the consortium. This free-of-charge access is provided in the frame of the VetBioNet EU funding to researchers or enterprises proposing high-quality projects related to epizootic and zoonotic diseases.
2. **Networking Activities (NA)** to foster the cooperation between project partners and to forge cooperative relationships with other European or international research initiatives, industrial stakeholders, international organisations and policy makers;
3. **Joint Research Activities (JRA)** to improve the scientific and technological standards of services provided by the consortium.

VetBioNet brings together 27 partners from 12 different countries across Europe, Africa, and Oceania (France, Germany, The Netherlands, Denmark, United Kingdom, Spain, Italy, Switzerland, Poland, Ireland, Kenya and Australia).

VetBioNet principal objectives are to reinforce the cooperation between Europe's leading high-containment research infrastructures, to provide access to the high-containment research facilities of the network, and to further improve the technical standard of the services provided.

Before the start of the ERG, the VetBioNet H2020 project has developed some assets that serve as a basis of the VetBioNet ERG.

The VetBioNet H2020 project provided academic and private research communities with free-of-charge and easy access to BSL3 facilities and expertise to support zoonotic and epizootic research.The VetBioNet H2020 project also provided training and best practice guidelines for high-containment laboratory/animal facility experimentation and ethics, as well as new approaches to animal experimentation and alternative models to reduce animal use according to the principals of the 3Rs: replacement, reduction, and refinement.

Research activities of the VetBioNet H2020 project have allowed the development and validation of new analytical tools, reagents and methods to help interrogate the host-pathogen interaction (immunogenetics, NanoString or Fludigm transcriptomics, diagnostic polyclonal and monoclonal antibodies to name just a few) and to study animal behavior in an infectious context (prototype of

telemetric sensors and behavioral analysis software) as well as alternative in vitro models for infectious studies (cell lines, 3D cellular models).

The VetBioNet H2020 project has produced:

- Best practice guidelines for the management of biocontained animal facilities and laboratories and ethics for animal experimentation, available on the public e-learning platform on VetBioNet website.
- Detailed protocols (culture, cell infection, establishment of alternative in vitro models, state-of-the-art approaches for imaging interactions between live pathogens and host cells)
- Education and training dedicated to researchers or animal caretakers in different sectors, such as industry and academia (3Rs, Biorisk biosafety and Biosecurity management, analytical approaches for the study of host-pathogen interactions)
- Databases (cellular and animal models for research in animal infectious disease research, and 3R tools) and a public e-learning platform (course materials, best-practice guidelines and protocols produced by VetBioNet) available on the VetBioNet website.

In the VetBioNet ERG, activities will include:

1. TNA activities: Facilitate access to facilities for veterinary infectious diseases research projects. The free-of-charge access previously available through VetBioNet funding will no longer be offered as part of the ERG. However, the ERG will facilitate and support free-of-charge TNA access through ISIDORe (EU Horizon Europe, 2022-25, Grant Agreement No 101046133) funding, seek future opportunities for TNA funding and act as a hub to support access to VetBioNet partner institutions on a commercial basis. One critical aim of these activities is to compile a constantly updated catalogue of services available at the VetBioNet-ERG partner infrastructures.

2. Networking activities: Explore network sustainability patways. Harmonize and standardize procedures, notably in the areas of biorisk management, ethics and 3Rs, including the use of new alternative in vitro models.

- Organize meetings to discuss sustainability options and funding opportunities among the ERG partners.
- Provide expertise for training to researchers in experimental design, biohazards, ethics, the 3Rs, and in analytical approaches for the study of host-pathogen interactions.
- Maintain and share the network's unique databases in the field of veterinary infectious disease research (cell and animal models, 3Rs tools) and the e-learning platform compiling all VetBioNet productions (course materials, best-practice guidelines and protocols).
- Organize meetings to promote exchanges between VetBioNet partners and the community in the field veterinary infectious diseases.
- Showcase and disseminate VetBioNet-ERG activities and their results through the VetBioNet website and Newsletters.

3. Joint Research Activities (JRA):
Explore funding opportunities to support research in infectious diseases of veterinary species that could be proposed in the context of future fundings/calls including:

- new and improved models/tools to improve the analysis of responses to infection and the host pathogen interaction;
- new and improved vaccines and diagnostic tools;
- other areas of interest to the ERG including epizotic and zoonotic diseases at the wildlife/livestock/human interface.

ANNEX 2

SPECIFIC STATUS OF KNOWLEDGE DEVELOPED PRIOR TO THE SIGNATURE OF THIS ERG AGREEMENT

The partners agree that the following listed tools, developed in the frame of the VetBioNet EC funding period, will have the following conditions of use under the ERG framework.

All VetBioNet partners will have access rights (reading and writing of content) to the web-based tools listed below:

- VetBioNet Deliverables and Milestones;
- VetBioNet Databases: animal and cell models (public data only), 3Rs network and 3Rs tools;
- e-Learning plateform.

The tools below will also be accessible to the public (reading):

- VetBioNet Deliverables and Milestones (public ones only);
- VetBioNet databases: animal and cell models (public data only), 3Rs network and 3Rs tools;
- e-Learning plateform.

The VeBioNet public website will remain accessible to the public.

ANNEX 3

COORDINATOR AND COMPOSITION OF THE EXECUTIVE COMMITTEE AT THE DATE OF 28th February 2023

The Parties on the ERG Agreement entitled "**VetBioNet-ERG**" hereby appoint the WP Leaders of the VetBioNet EU project and one representative for each of the founding partners as members of the Executive Committee of VetBioNet-ERG:

list of members (RI) and coordination

ANNEX 4

LIST OF THE TASKS OF THE ERG AT THE DATE OF 28th February 2023

The Parties of the ERG Agreement entitled "VetBioNet-ERG" hereby decide to launch the following tasks in the frame of the ERG at the date of 28th February 2023:

- Task 1: Coordination of the VetBioNet-ERG by the Coordinator (…)
    - Provision of a management structure for the coordination of the VetBioNet-ERG and the represention of the Parties in joint funding bids or EU projects integrating the activities of various Research Infrastructures or networks;
    - Organisation of bi-annual meetings of the Executive Committee (Task leader assembly) and draft and circulation of meeting minutes;
    - Organisation of annual meetings of all Parties (General Assembly) and and draft and circulation of meeting minutes;
    - Draft and circulation of annual reports (VetBioNet-ERG activities and use of personnel and financial ressources);
    - Advertisment of the VetBioNet-ERG activities to sponsors (industries, funding organisations supporting collaborative networks or conferences).

- Task 2: TNA platform for the promotion of VetBioNet TNA/services. Task leader(s): …
    - Compilation of research services available at the VetBioNet-ERG facilities (VetBioNet service catalogue);
    - Mapping of European and international research infrastructure capacities to respond to veterinary infectious disease threats;
    - Identification of gaps in the VetBioNet service catalogue;
    - Collection of Joint Research Activities topics addressing the VetBioNet service gaps.

- Task 3: Sustainability platform for the exploration and creation of collaboration or funding opportunities to maintain the integrating activities (TNA, Networking Activities, Joint Research Activities) performed in the VetBioNet project. Task leader(s): …
    - Cooporation with other European Research Infrastructures or networks operating in the field of veterinary infectious diseases and One Health to devise a common research strategy and sustainability plan;
    - Mapping of international, European and national funding opportunities;
    - Preparation of joint comments on pre-publications of EU RIA programme topic drafts (e.g. INFRA-SERV, INFRA-TECH);
    - Promotion of research priorities related to veterinary infectious diseases in the national and European agendas;
    - Promotion of the preparation of joint funding proposals (between the Parties or the VetBioNet-ERG and other Research Infrastructures or networks).

- Task 4: Networking Activities platform for fostering continuous exchanges and activities centred on the VetBioNet-ERG topics listed below. Task leader(s): …

    - Best practices in bio-contained animal facilities for terrestrial and aquatic species;
        - Continous cooporation with the International Veterinary Biosafety Workgroup (IVBW) and the Group of High-containment Laboratory Directors (GOHLD);
        - Maintenance of the VetBioNet page on the IVBW website;
        - Update and creation of best practices guidelines.
    - Bioethics, 3Rs and public perception of veterinary infectious disease research;
        - Continious cooperation with FRAME (Fund for the Replacement of Animals in Medical Experiments) and other stakeholders in the field of the 3Rs (Replacement, Reduction, Refinement);
        - Maintenance of the 3Rs network and tools database on the VetBioNet website;
        - Update and creation of bioethics/3Rs guidance documents.
    - Other topics identified by the Parties.

- Task 5: Joint Research Activities platform for pursuing or developing research collaboarations in the fields indicated below. Task leader(s): …
    - Live animal models for infectious diseases;
    - Alternative models for infectious diseases;
    - Vaccines and diagnostic tools;
    - Bioimaging;
    - Sensor technologies for clinical and behavioural monitoring;
    - Other research fields (VetBioNet service gaps) identified by the Parties.

- Task 6: Dissemination platform for sharing VetBioNet-ERG news and results. Task leader(s): …
    - Update and maintenance of the VetBioNet website;
    - Update and maintenance of the VetBioNet databases (animal and cellular models, 3Rs network and 3Rs tools) and the VetBioNet e-Learning plateform.
    - VetBioNet-ERG Newsletter
    - Announcement of VetBioNet-ERG news and events (e-mail, website)

These tasks shall be modified, deleted or new ones created in functions of the needs and of the strategy of the ERG decided by the General Assembly.

ANNEX 5

ERG's PROVISIONAL RESOURCES AT THE DATE OF 1st February 2023

The Parties of the ERG Agreement entitled "**VetBioNet-ERG**" hereby agree to commit the following in-kind resources at the date of 1st February 2023 over a one year renewable period:

Name	Efforts (in pm)	Other in-kind contribution	Allocation
INRAE	tbd	tbd	*examples* *Task 1: Coordination of the ERG: coordination and monitoring of Tasks 1 to 6 and development of a strategic plan for the activities of the ERG.* *Task 2: Contribution to all activities of the TNA platform (through the INRAE Access Providers and the ISIDORe WP11/WP14 lead).* *Task 3: Contribution to all activities of the Sustainability platform.* *Task 4: Contribution to all activities of the Networking Activities platform.* *Task 5: Active contribution to selected Joint Research Activities; contribution to the discussions on priority Joint Research Activities.* *Task 6: Support of the Dissemination platform in all of its activities.*
MRI			
FLI			
TPI			
APHA			
INIA			
IRTA			
EDI-IVI			
PIWET			

AU			
ANSES			
UEDIN			
EMC			
IZSVe			
UNOTT			
NUID UCD			
ILRI			
CSIRO			
EAAP			
ISX			
LEICA?			
Noldus			
EpiBio			
VAL			
INGENASA			
TOTAL	**pm**		

These in-kind contributions are understood as number of person-month/year of staff that will be dedicated to the Tasks and the Governance of the VetBioNet ERG (including the Coordinator, the Executive Committee and the General Assembly). It is understood that the partners agree to allocate to these persons the corresponding budget to cover their work in the VetBioNet ERG: access to a computer and IT services, consumables related to their work, overheads, travel and subsistence whenever needed, etc.

Once a year, the Coordinator will ask every partner to report on the use of these efforts and to justify it in relation to the work achieved in the VetBioNet ERG.

ANNEX 2

EDRI consultation paper

European Epidemic Disease Research Infrastructure:

Rapid Research for Prevention and Control of Emerging and Epidemic Disease

Draft 24.06.2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N°731014

This document is a joint consultation by coordinators and directors of five EC infectious disease INFRAIA projects and ESFRI research infrastructures listed below. It presents a plan to leverage inherent complementarities of existing EC resources to achieve greater impact against emerging, including re-emerging, and epidemic disease.

Statement of the problem

Infectious disease emergence and epidemics pose important new challenges for human and animal health. Large scale and systemic environmental impacts of globalization including climate change and ecosystem disturbances are expected to increase the frequency and intensity of disease emergence and epidemics.

Context of the problem

The One Health approach recognizes the essential links between the health of humans, animals and ecosystems. At least partly due to climate change and ecosystem disturbances, a number of vector-borne infectious diseases, formerly prevalent mainly in the Southern hemisphere, are today spreading also within Europe (West Nile fever, dengue fever, chikungunya fever, Zika, Crimean-Congo haemorrhagic fever, Bluetongue disease, leishmaniasis, etc.). Mild winters have dramatically altered the population dynamics of certain wildlife species, which can act as reservoir hosts or directly transmit high-impact epizootic or zoonotic diseases (e.g., wild boars transmitting African swine fever or bovine tuberculosis to domestic pigs or humans). The coronavirus disease 2019 (COVID-19) pandemic, which jumped from an animal source (bats and an unknown intermediate host) to humans, may not be directly climate-driven, however it is suspected that the soaring frequency of bush fires driven by global climate change will favour the (re-)emergence of other bat-transmitted zoonotic diseases, e.g. rabies or henipavirus infections. Indeed, as climate patterns change many ecologically stressed animal populations will be pushed into more frequent contact with humans and livestock animals. This and other factors such as wild animal trading will increase the opportunity for shifts in pathogen tropism and new disease emergence. In addition, the geographic movement of humans, animals and vectors exposes pathogens to naïve populations, making pathogen adaptation more likely, and increasing the risk of disease transmission to potentially millions of Europeans. Understanding the mechanisms and conditions of these new disease dynamics is imperative for the rapid development of tailored diagnostics and interventions to combat the spread of diseases and/or vectors.

Solution proposed

Create a European ***Epidemic Disease Research Infrastructure (EDRI)*** cluster comprised of five existing EC infectious disease research infrastructures and projects, supplemented by resources as needed from other relevant existing EC research infrastructures and projects. Linking these world-leading infrastructures and resources will create synergies and foster a coordinated approach to enable rapid research and development of needed tools and technologies, and enhance the European capacity for the control of emerging and epidemic infectious diseases. Augmented European rapid research capacities for epidemic control in a One Health perspective will contribute to the EU Mission area on "Adaptation to climate change", the European Green Deal, and the United Nations Sustainable Development Goals.

Means

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N°731014

Four current INFRAIA projects and one ESFRI research infrastructure, (hereafter referred to collectively as the 5 RIs) offer specialized infrastructures and support services for research on infectious diseases. Fostering increased interconnection and integration among these RIs, in association with other existing EC research infrastructures and projects, will create a rapid research capacity to improve responses to emerging and epidemic infectious diseases in Europe. The existing five RIs have complementary missions, expertise and facilities. Leveraging these existing strengths to develop complementarities and synergies will create an additional value, boosting the European Research Area in innovation for public and veterinary health.

i) Five INFRAIA projects and ESFRI research infrastructures on infectious disease are the core "5 RI eyes" of the proposed EDRI cluster for epidemic preparedness and response:

- ERINHA – An international non-profit organization supporting research on high-consequence pathogens with important impact on human health and providing access to European high-containment BSL3 and BSL4 laboratories and expertise. The "European Research Infrastructure on Highly pathogenic Agents" is a legally established infrastructure, landmark on the ESFRI roadmap and coordinator of "ERINHA-Advance" GA n° 824061
- EVAg – The globally largest archive of virus strains including highly contagious human, animal and plant pathogens, with strong links with the industrial sector, large companies and SME. "European Virus Archive – global", INFRAIA GA n° 871029
- InfraVec2 – Supporting all aspects of research on vector-borne disease of humans and animals, including BSL3 facilities for arthropod infection, novel field diagnostics for surveillance, vector control tools, and study of environmental parameters that promote disease transmission. Includes partners in front-line disease emergence zones, and field sites for epidemiology. "Research Infrastructures for the Control of Vector-borne Diseases", INFRAIA GA n° 731060
- TRANSVAC2 – Accelerated development of new vaccines with a One Health focus on infectious diseases of humans and animals. "European Network of Vaccine Research and Development", INFRAIA GA n° 730964
- VetBioNet – Infrastructure resources for research on epizootic and zoonotic diseases in livestock, aquaculture and wildlife species, including high-containment BSL3 facilities. Includes WHO/OIE and European and National Reference Laboratories for epizootic and zoonotic diseases with expertise and infrastructures for research on host adaptation and intra- and interspecies transmission of emerging pathogens. "Veterinary Biocontained Research Facility Network", INFRAIA GA n° 731014

The five RIs gather tremendous scientific resources to address the health challenges posed by infectious disease emergence and epidemic spread. VetBioNet & ERINHA provide outstanding capacities for the study of highly pathogenic agents of animal and human origin. InfraVec2 offers expertise and facilities for the study and control of highly pathogenic diseases transmitted by insects and ticks. TRANSVAC2 is specialized in vaccine development and is already supporting the development of vaccines against emerging infectious diseases including COVID-19. EVAg produces, characterizes and distributes virus-related materials, including virus strains and diagnostics tools. Thus, the constituent five RIs can offer a complete pipeline of epidemic response research services from field to medical countermeasures.

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ii) The facilities and expertise of additional existing EC research infrastructures and projects could provide important support as potential partners in the EDRI cluster. This list is draft and indicative only, and does not yet represent involvement of all of the named entities:

- BBMRI – biobanking resources (ESFRI).
- ECRIN – human clinical trial support (ESFRI).
- EATRIS – translational support for therapeutics, diagnostics (ESFRI).
- ELIXIR – open data and information resources (ESFRI).
- EU-OPENSCREEN – European high-capacity screening (ESFRI).
- MOOD – big-data epidemiology and epidemic tracking resources (H2020-Single-Stage-RTD RIA).

Proposed actions of the EDRI cluster

The EDRI cluster activities will be undertaken in three related phases, according to the epidemic situation. The overall goal is to augment resilience and resistance to epidemics of humans and animals including livestock industries, in Europe and globally.

- 1. Inter-epidemic period. During inter-epidemic 'peace-time', the focus is on early detection of pathogen emergence, outbreak prevention, and strengthening preparedness for eventual epidemic response. Activities include use of the RIs to:
  - Carry out field studies on the prevalence of pathogens that are candidates for emergence and outbreak in animal or human hosts using RI field sites and resources.
  - Understand the biology of disease emergence and re-emergence by host shift from animal to human, and/or shift to a more efficient insect vector or reservoir host.
  - Develop tools and technologies for candidate diseases prioritised by outbreak potential, such as molecular diagnostics for pathogen and vector, initial serological tests, and immunological studies aimed at vaccine development. Particular emphasis will be given to the WHO List of Blueprint priority diseases for research and development.
  - Test therapeutics or drugs in pre-clinical studies for pathogens (or genus relatives) considered to have epidemic concern or potential (e.g. WHO Blueprint list)
  - Develop animal models and tools to study pathogen adaptation and transmission mechanisms in a wide range of wildlife host species relevant to disease (e.g., passeriform birds, bats, wild carnivores, camelids and feral pigs), in order to have models and tools available for studying pathogen XY originating from or affecting a given host.
  - Strengthen research & response capacities of existing partners in disease emergence zones.
  - Develop formal links with international and national public health and epidemiology bodies, in advance of an epidemic crisis.
  - Support the development of platform technologies that will allow the rapid development of preventive and therapeutic tools in case of outbreaks.
- 2. Epidemic crisis period. The nature of crisis response during an outbreak or epidemic will depend on the specific hosts, pathogens and vectors. Access to the RIs is essential for rapid research to:
  - Finalise and rapidly distribute molecular diagnostics for the pathogen in humans, wild or farmed animals, and insect or tick vectors if vector-borne.
  - Finalise and rapidly distribute serological tests for human or animal host exposure.
  - Carry out animal infection studies to determine the pathogen's host range and to identify the most appropriate infection models for pre-clinical studies.
  - Carry out initial serological and immunological studies aimed at vaccine development.
  - Determine specific vector species and appropriate means of vector control, if relevant.

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- Develop in vitro cell or tissue culture infection models with the epidemic pathogen, if appropriate, for initial exploration of licensed drug efficacy.
- Actively support the accelerated development and testing of preventive and therapeutic tools to combat outbreaks.

- 3. Epidemic post-crisis period. The RIs are implemented in the post-crisis period for basic and translational research to:
- Study the function and biology of the epidemic pathogen, host immunity, pathogenesis, pathogen-host and vector interactions.
- Assemble cohorts of humans, livestock animals or animal models.
- Continue the development of preventive and therapeutic tools.
- Determine vector competence and geographic risk distribution of vector species, and vector control tools, if relevant.

Expected results and milestones

- Rapid task force evaluation of any new emergence will direct the research response:
- Initiate immediate communication for joint coordination with appropriate mandated public health bodies and networks (e.g., ECDC, GloPID-R, EPIZONE, WHO, FAO, OIE), according to human or animal disease emergence.
- The characteristics of the emerging disease (e.g., virus, bacteria, parasite, prion, animal, human, possible vector-borne, possible Risk Group 4 pathogen) will determine which RIs within the EDRI cluster are most appropriate to lead the response.
- The EDRI cluster issues and publicizes immediate specific calls for research community access to TNA resources.
- The EDRI cluster initiates rapid joint research actions as described.
- Rapid development of new disease diagnostic and intervention tools, such as:
- Reference materials (e.g., pathogen isolates, infected tissues, genomic resources and reference sera).
- New diagnostic kits and tools to detect potential or emerging pathogens.
- New surveillance tools including field based as well as big-data to monitor spread of infected vectors or animals.
- Novel vaccines to protect from emerging infectious diseases.
- New therapeutic tools to combat pathogens.
- New environmentally sustainable “green” vector control tools.
- Fast-track services, such as:
- Rapid activation of epidemiological field surveillance sites and teams mobilising existing field sites and resources.
- Rapid shipping and distribution processes for reagents, kits, tools.
- Rapid basic training for end users of reagents, kits, tools.
- Rapid pathways to ethics and regulatory approvals.
- Leverage the existing constituent five RIs and associated resources and expertise to strengthen epidemic response
- Integrate with epidemic response bodies and authorities including the ECDC, Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), the European Research Group on animal disease (EPIZONE), WHO Regional Office for Europe, FAO, OIE and relevant key national ministries of health, in order to link research and technology development directly to epidemic preparedness and response.
- New predictive risk models for spread of infected vectors and animals.
- New tools for management of environmental conditions conducive to disease and vector spread (wild animal reservoirs, vector breeding sites).

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- Thematic integration of complementary research activities and services under a common One Health approach for sustainable control of emerging infectious, vector-borne and zoonotic diseases.
- Creation of a joint catalogue and portal of newly developed research services and technologies tailored for emergence and epidemic response.
- Creation of a public repository showcasing output of the EDRI activities.
- Creation of a joint steering committee comprised of the constituent five RIs coordinators to promote complementarities, develop integrated research services to rapidly confront newly emerging epidemics, and determine research priorities in conjunction with epidemic response bodies and authorities.

Metrics to determine impact

- Numbers of requests for new emergence and epidemic research services.
- Numbers of new disease control tools added to the joint catalogue for emergence and epidemic response.
- Ultimately resulting from successful use of preventive interventions (vaccines, vector and animal reservoir control) will be the reduction of morbidity and mortality attributed to emerging infectious diseases.
- Resulting from successful use of control tools for disease vectors or animal disease reservoirs will be the reduction of prevalence of infected vectors or animals.
- Ultimately resulting from successful inter-epidemic 'peace-time' activities will be early detection and response to pathogen emergence such that potential outbreaks are prevented, although outbreak prevention is difficult to measure.
- Research output measured by publication citations and data use credits.
- Numbers of website visits and social media references.

Administrative placement of EDRI cluster

The administrative form of the proposed Epidemic Disease Research Infrastructure remains to be determined. Several options can be considered from short to long time frames. As a practical first step, the five initiating RIs can cooperate as a dedicated cluster for epidemic research within the new Horizon Europe framework programme. This would require the issuance of a targeted call to which we could respond. The thematic EDRI cluster would enable common service-providing, enhancing of common scientific capacity, and will generate visibility of the EDRI undertaking to relevant European and international stakeholders as well as public and private users.

A cluster type structure may also have some limitations, as it would not enable a long-term sustainability of the initiative. However, this weakness is expected to be outweighed by the opportunity to develop close cooperation on the above-mentioned actions, thus demonstrating tangible scientific results, visibility and recognition by relevant bodies and stakeholders. In the long run, such an organization will depend upon the sustainability insured to the component entities of the EDRI, but the precise modality of sustainability, discussed further below, could be developed during the lifespan of the EDRI cluster.

This initial EDRI cluster would create a large scientific space to advance outbreak and epidemic research based on the infrastructures and expertise of the existing 5 RIs, and at the same time dedicate effort to identifying other associated cluster partners, and developing a sustainable long-term EDRI format. The EDRI cluster should be highly visible within partnerships as the EU-Africa Global Health Partnership, and the new European

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Partnership on Pandemic Preparedness and Societal Resilience, both currently under consultation.

The proposed Epidemic Disease Research Infrastructure is built of existing complementary RIs. Significant added value could be obtained by simply integrating them as a dedicated cluster of specialized infrastructures, scientific expertise, field study sites, and reference laboratories to augment preparedness and prevention. A dedicated cluster would be a first step to integrate the existing RIs in a provisional format, in which the EDRI cluster would support and be available to be mobilized by ECDC, WHO, OIE and other mandated governmental and nongovernmental bodies as needed for a given epidemic research response, without necessarily requiring formal attachment to these permanent mandated government body. The initial activities of the EDRI cluster would establish operational links and priorities among the five RIs, relationships with mandated bodies, and would be branded to generate long term high confidence.

Other than a dedicated EDRI cluster, there are possible alternative pathways of structuring of the EDRI initiative. First, establishment of the EDRI could be considered through the European Joint Programming Initiatives mechanism (similar to the European Joint programme on rare diseases EJP RD, or One Health EJP). Some of our missions may be particularly complementary with this latter initiative. A second alternative to the cluster approach could be to establish the EDRI as a coordination body tightly linked with mandated international health organizations for humans, animals and plants. This EDRI coordination body would include coordinators of the RIs involved, and would be mobilized to organize a dedicated action plan to be implemented by the RIs concerned by the issue.

As a long-term perspective the proposed EDRI initiative would be most effective as a sustainable entity associated to a mandated permanent European governmental or non-governmental body (e.g. ECDC, the Joint Research Centre of the EC, or the WHO Regional Office for Europe), or as an independent entity backed up politically and financially by EU member states and other relevant institutions. The COVID-19 experience highlights the crucial role and credibility of ECDC for the EU epidemic response, but also the need for the ECDC presence to be stronger, which could be achieved in part by the association of a dedicated research infrastructure.

Risk factors

- Necessary collaboration with research partners from disease emergence or epidemic countries may be delayed by regulatory or research authorization barriers for access to samples, study cohorts of humans and/or animals, data or field sites.
- The EDRI could have diminished usability for epidemic response and public health bodies if temporary and not stably anchored within a perennial structure of the EC.
- Lack of funding to ensure the long-term sustainability and perform high-level research, as the priorities of funding organizations often change, once an epidemic/pandemic crisis is over.
- A consequence of efficient inter-epidemic 'peace-time' activities could be that policy makers perceive successful early outbreak detection and epidemic prevention as absence of risk, thus weakening political will to support essential prevention and preparedness activities.

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Coordination, specific actions, initiatives and measures

The above constituent five RIs comprising the EDRI cluster should be incentivized to commit parts of their wider thematic support services towards contributing to the joint goal of developing rapid research responses to emerging, re- emerging and epidemic diseases. Concretely, this new specific goal will be achieved and monitored by a joint EDRI cluster steering committee of the "5 RI eyes" coordinators and RI directors. Additionally, a specific secretariat should be put in place from mid-to-long term perspective, with dedicated functions which will be fully dedicated to the network functioning, service-providing, scientific management and communication. In this case the Steering Committee will be a decision-making and governance body. An independent Advisory Board will ensure the scientific advice for the network and evaluation for scientific service providing.

The coordination will be implemented according to agreed governance practices, and will be flexible to allow eventual inclusion of additional relevant research infrastructures or projects, for example on social science, big-data ecology and climate modelling, or medicinal and structural chemistry.

Linkage to ongoing EU activities and policy initiatives

The proposed interconnection and integration of individual projects and research infrastructures to create the EDRI cluster is needed to achieve the EU's 2030-2050 climate goals, in terms of mitigation of the disease and epidemic impact of climate change in a sustainable One Health approach. The EDRI cluster should be linked with and provide guidance to the planned EU-Africa Global Health Partnership on research activities addressing human and animal infectious disease in Africa, including transboundary livestock diseases, neglected tropical diseases, malaria and other vector-borne diseases. Facilitated research on the control of disease vectors also contributes to the EC Joint Research Centre policy dossier "Toward climate change impact: Vectors carrying viral infections". The proposed EDRI cluster is a contribution to the European Green Deal by fostering a One Health conception of adapting to the negative effects of climate change upon human and animal health, as also proposed under UN Sustainable Development Goals 3 and 13 (Good health and well-being/Take urgent action to combat climate change and its impacts).

Prospects for large-scale adoption

Integration of the EDRI cluster joint steering committee into relevant large research undertakings (e.g., the EU-Africa Global Health Partnership, and the European Partnership on Pandemic Preparedness and Societal Resilience) and epidemic response bodies and authorities (e.g., ECDC, GloPID-R, WHO, OIE) will ensure use at-scale of the emergence and epidemic response research services by a large European research community in partnership with international disease origin countries and interested global funders. Additionally, it will enable a coordinated approach among an enlarged stakeholder base for rapid research response to infectious diseases outbreaks.

Required financing and sources

Based on anticipated new activities, an estimated € 10 million per year will provide for specialized rapid research services activities and services dedicated to the prevention, preparedness and control of emerging and epidemic infectious disease, including those

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expanding due to climate change. A partial list of new activities and services are those above in “Expected results and milestones”.

Broad categories of activities will include research on pathogens, surveillance, mitigation measures, diagnostic development, vaccine development, pre-clinical model development, training for diagnostic usage, as well as classic transnational access to research infrastructure facilities. Activities are classified as inter-epidemic ‘peace-time’, epidemic crisis period, and epidemic post-crisis. Each of these require distinct but equally important and interlinked activities. Inter-epidemic ‘peace-time’ activities are as essential as crisis response, because each epidemic successfully prevented or detected early can represent a large economy in lives, disruption, and cost. Recent experience with Zika virus and COVID-19 has shown that in an epidemic situation, R&D, production and logistic costs can quickly consume the partner provider budget. Under the new proposed EDRI cluster, the EDRI cluster joint steering committee will adopt a flexible mechanism to rapidly allocate contingency funds to the points of need. Initial financing would be anticipated from EC sources.

The integration of the existing world-leading infrastructures to create the EDRI cluster will create an unprecedented one-stop shop of infectious disease and vector research capacities and facilities. Joint business development actions will leverage the EDRI cluster to appeal to potential customers. These could include non-EU governments, commercial users, and commercial investors. Some of the existing five RIs already include a significant proportion of commercial entities as partners, and engage in exchanges with external commercial users.

Community and stakeholder involvement

Integration of the above EDRI cluster with the EU-Africa GHP and epidemic response authorities listed above will directly expose the component providers of specialized research services to all relevant stakeholders participating in these initiatives. Uptake and use of the new catalogue of specialized research services for emergence and epidemic response as outlined above (“Expected results and milestones”) will be dramatically enhanced. Research on emerging epidemic diseases resulting from human-animal contact, as well as vectors transmitting infectious diseases formerly prevalent only in the Southern Hemisphere, naturally builds on existing collaborations of the constituent five RIs with international research partners in disease emergence zones outside the EU. Therefore, this proposed joint effort for rapid research response to emerging and epidemic disease clearly calls for wider international cooperation and global scope.

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ANNEX 3

Memorandum of Understanding (VetBioNet / ERINHA)

MEMORANDUM OF UNDERSTANDING BETWEEN

The European Research Infrastructure on Highly Pathogenic Agents (ERINHA-AISBL)
&
The Veterinary Biocontained facility Network for excellence in animal infectious disease research and experimentation (VetBioNet)

WHEREAS, emerging and re-emerging zoonotic infectious diseases are a major public health problem worldwide and developing medical countermeasures is crucial for preventing and treating them.

WHERAS, the One Health approach recognizes the importance of the multidisciplinary and multisector collaboration to attain optimal health for people, animals and our environment.

WHEREAS, research infrastructures are considered to be crucial to sustain scientific and technological progress and strengthen the research and development community;

WHEREAS, the mission of VetBioNet is to establish and maintain a comprehensive network of pre-eminent high-containment (BSL3) research facilities, academic institutes, international organizations and industry partners that is dedicated to advance research on epizootic and zoonotic diseases and to promote technological developments.

WHEREAS, the mission of ERINHA-AISBL is to contribute to protect human health by advancing high-containment research and increasing European and global preparedness for and capability to respond to highly infectious disease threats.

NOW, THEREFORE, within the framework of the Statutes of each entity, INRAE, on behalf and as coordinator of VetBioNet and ERINHA agree to collaborate and align their efforts regarding the better use and development of VetBioNet and ERINHA research infrastructures as well as the promotion of the One Health approach.

The means for the in-depth collaboration and efficient use of the research capacities of the VetBioNet European initiative and the ERINHA research infrastructure, include, but are not limited to:

- Sharing information and experience
- Cooperating in the field of service provision
- Sharing best-practices and research results if permitted by existing confidentiality agreements
- Strategically planning and aligning activities

It is anticipated that the collaboration could occur through following activities:

- Alignment of activities of mutual interest
- Subcontracting of services / mutual provision of services
- Joint communication activities
- Cooperation for a set-up of a larger European initiative in the field of research on infectious diseases with epidemic / pandemic potential
- Any other means deemed useful by both parties

It is acknowledged that each party may possess confidential information within its entity and from independent third parties. This information would only be shared between the parties under a specific confidential disclosure agreement and for the latter with the permission of the third party whose information would be shared.

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This Memorandum of Understanding is a non-binding document that creates no rights and imposes no obligations on either party.

Upon signature by each party, this MOU shall be in effect up to February 28 2022 or until otherwise terminated in writing by either party to other Party with at least one (1) month notice of intention to terminate.

Done at Paris, France on …….. 2020 in two originals.

For ERINHA	For VetBioNet
Name:	Name:
Title:	Title: coordinator

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