

Next Generation Biobanking

QMS Improvements Impact Research Output

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<http://global.european-virus-archive.com/>

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EVAg is a non profit organisation that mobilises a global network with expertise in virology to **authenticate** viruses and derived products.

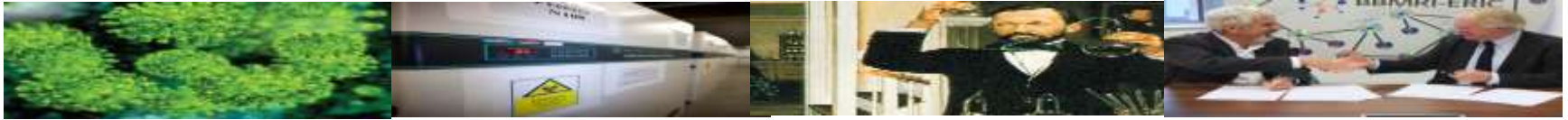
A unique Biological resource, in the field of virology, readily available online. Users may benefit from special funding to access to products of interest, do not hesitate to apply.

[Start browsing through our viruses and related products](#)

- 
A network of laboratories
 An inter-national group of 25 laboratories, including 16 EU member state institutions and 9 non-EU institutions, that represent an extensive range of *microbiological* disciplines.
- 
Quality
 We highly take into consideration the quality of the viruses and derived products added to our catalogue. Improvements on quality process will be addressed during the project.
- 
Research
 Focused on the creation of new tools, techniques and concepts to develop the infrastructure and to provide easier and less expensive access to virological materials.
- 
Collaborations
 An open society aiming at developing synergies and complementary capabilities, to study a way as to offer an improved access to researchers.
- 
Preparedness and Response
 EVAg generates and distributes *quality* diagnostic materials and products in the event of epidemiological emergencies.
- 
Online Catalogue
 A user-friendly web Portal with a continuously increasing number of viruses and derived products. [Start here](#).

<p>25 Partner Laboratories</p>	<p>1300 References in our catalogue</p>	<p>700+ Online Enquiries</p>	<p>1600 Items ordered</p>
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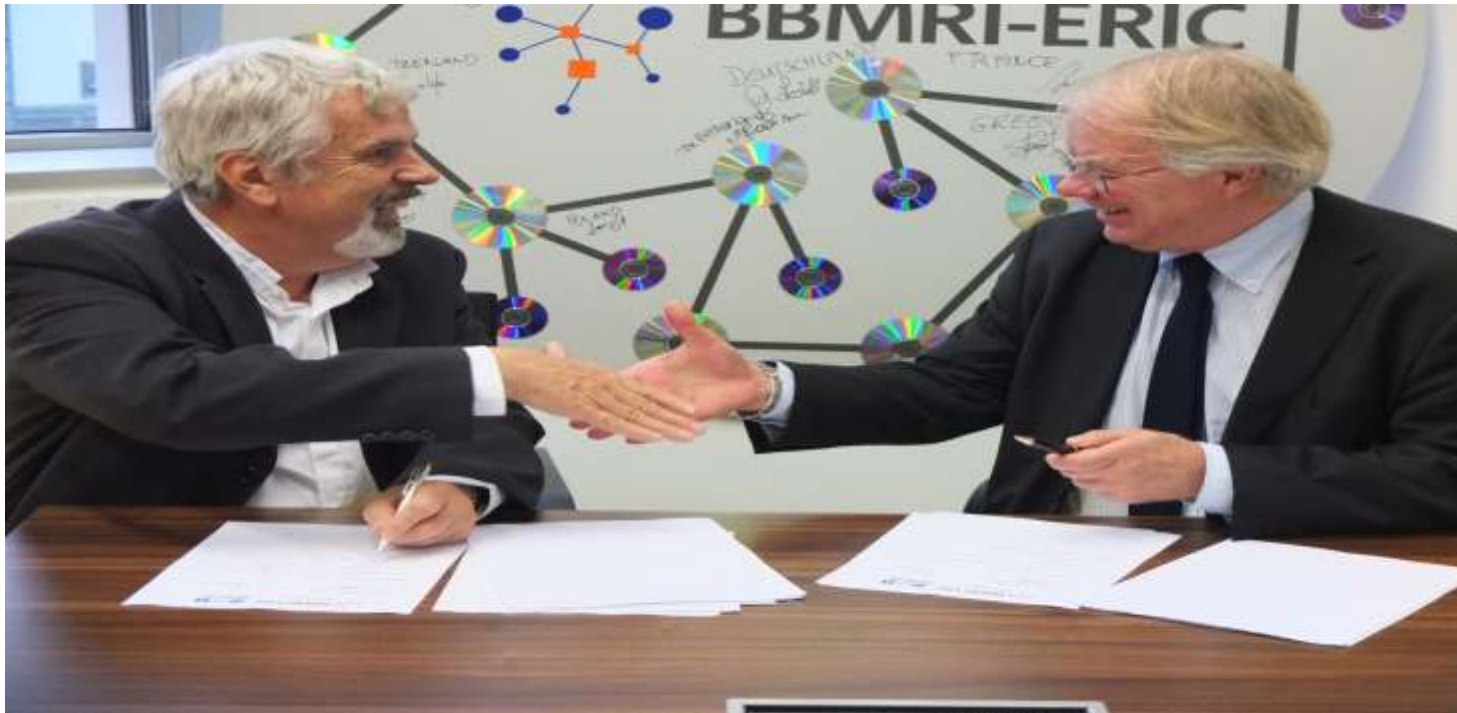


▶ The EVA Global Project & BBMRI

- ▶ The European Virus Archive (Global) continues and expands the original EVA (FP7) project from 9 European labs to 26 worldwide labs, plus >12 associated partners.
- ▶ H2020 funding plus national government support for associate labs.
- ▶ EVAg's principal aim is to provide access to high grade resource material to support virus research and development of vaccines, diagnostic kits & antiviral drugs.
- ▶ We do this by populating a web-based catalogue of virus isolates and derived materials stored at EVA partner labs.
- ▶ Harmonisation / improvement to EVA labs' Quality Management.
- ▶ Memorandum of Understanding signed between EVAg and BBMRI-ERIC.

EVA Global & BBMRI

- ▶ EVA has signed a Memorandum of Understanding (MoU) with BBMRI-ERIC



Partner institutions



Projected associated partners

Associated partners in Japan, China, Spain, Russia, Jordan, Greece, Turkey and Sweden

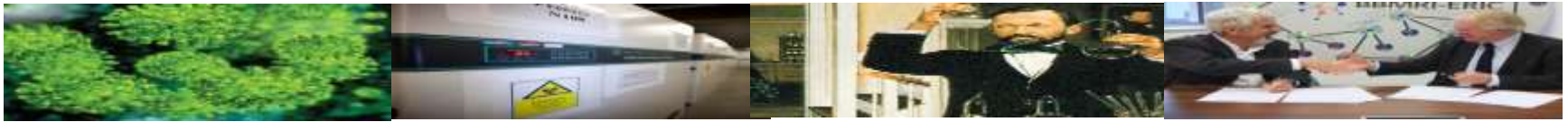
Associated networks: GABRIEL (Mérieux foundation) and Pasteur Institutes

The European Virus Archive goes GLOBAL

It is now an international group of **26** laboratories

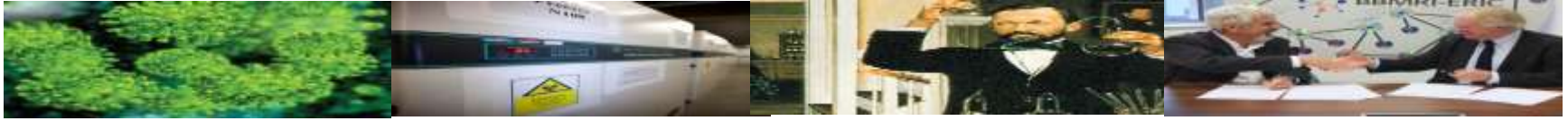
Including 17 EU and 9 non-EU research centers that represent an extensive range of virological disciplines.





▶ The EVA Global Project – raison d'être

- ▶ From Pasteur/rabies & Jenner/cow pox to the 21st Century & MERS CoV
- ▶ Early virus isolation & characterisation heralded a new era in veterinary and medical microbiology
- ▶ Virus collections grew according to the owning centre's specialism
- ▶ Poor or limited Quality Assurance – no ISO
- ▶ Legacy collections lack reliable provenance data. Poor or inconsistent records.
- ▶ Exchange only via collaboration or “Virus Club” personal contact
- ▶ Researchers complain that high quality samples are difficult to locate and acquire
- ▶ EVA was formed to connect researchers with high grade viruses and associated products



▶ The EVA Global Project – quality management philosophy

- ▶ Based upon ISO9001, but with additions. Aims to meet standards set out in OECD guidelines.
- ▶ Compliance with ISO9001 demonstrates process control, but does not assure high grade, just reproducibility!
- ▶ The EVA QMS aims to harmonise best practice in a virology lab, not all EVA labs are certificated / accredited to a Quality Standard.
- ▶ Labs that are accredited may not *necessarily* comply with the EVA requirements.
- ▶ EVA Global aims to provide high grade virus products and derived materials (recombinant proteins etc) to end-users. If partner labs fail to provide Quality Assured virus products, their sample resources will not be uploaded to the catalogue.

EVA Global - Critical Elements of QMS

- ▶ Job Descriptions – roles & responsibilities, skills needed
- ▶ Training Programme – continuing professional competence
- ▶ Staff Training Records – matches with JD and underscores laboratory skill set / suitability for the role
- ▶ Records Retention Policy – maintenance of provenance data adds value to virus samples
- ▶ Internal Audit Programme – self policing demonstrates commitment to the QMS and continuous improvement
- ▶ **Virus Specification – is it what I think it is?**

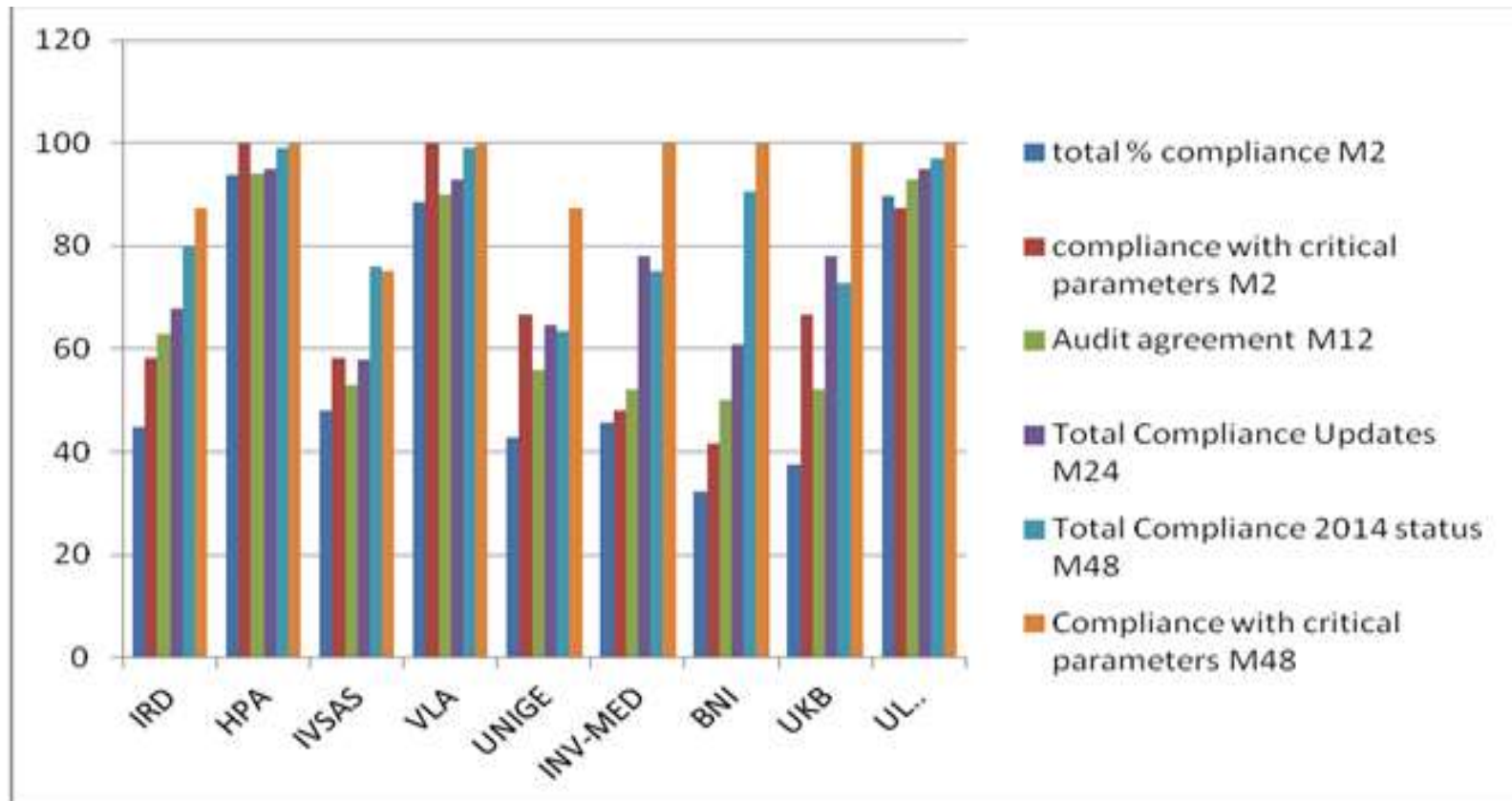


▶ The EVA Global Project

▶ *Virus Specification - confers product grade*

- ▶ Unique sample identifier
- ▶ Identity check: confirmatory sequence - partial or full
- ▶ Purity check: PCR to quantify mycoplasma content
- ▶ Viability check: infectivity & concentration
- ▶ Newly acquired virus - expand in cell culture to create Master stock & generate Working stock
- ▶ Storage & preservation (frozen or lyophilised). Ideally split 50:50 for disaster recovery
- ▶ Dispatch with Cert. of Analysis (name, accession & batch no., tests performed for viability, purity and identity)
- ▶ EVA Global products will be graded according to the extent of the specification
- ▶ **Gold Standard** = fully sequenced, mycoplasma free, lyophilised virus isolate of known concentration and infectivity titre.

Compliance Improvements Achieved Within EVA 2009 - 2014



Acknowledgements – EVA colleagues & The European Commission



EVA Global

- ▶ Thank you for your attention



MERS CoV – EVA's support to combat new disease



- ▶ Middle Eastern Respiratory Syndrome (MERS)
- ▶ Two cases of a rapidly progressive acute respiratory infection in adults associated with a novel coronavirus, detected in Saudi Arabia & Qatar
- ▶ Case definition by WHO – Sept 2012
- ▶ Collaborative activity co-ordinated by European and national epidemic response networks
- ▶ University of Bonn (EVA lab) developed diagnostic real-time reverse-transcription polymerase chain reaction (RT-PCR) assays suitable for qualitative and quantitative detection of the new agent
- ▶ EVA was mandated for the delivery of the assay reagents (positive controls): up to date more than 300 kits distributed worldwide to National Ref Labs
- ▶ Since Sept 2012, WHO states 1348 cases, 479 deaths (35%)
- ▶ No currently available vaccine



Disaster can strike... fortunately the EVA virology lab was on the floor below

