

Public Health Laboratories and IHR - Efficient response to highly dangerous and emerging pathogens at EU level

Joint Action EMERGE

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Best Practices in Implementing International Health Regulations
(IHR), Athens, 2018-6-7/8

EU-Joint Action EMERGE

JA “Efficient response to highly dangerous and emerging pathogens at EU level” (**EMERGE**) is focused on **laboratory management** of **cross-border outbreaks** caused by **risk group 3** and **risk group 4** new and dangerous **pathogens** which could cause **natural outbreaks**.

The activities are of particular value for Member States with less capacity and expertise to respond to threats caused by emerging and dangerous pathogens and it will support Member States in implementing the **Decision 1082/2013/EU** and the **International Health Regulations**.

Decision 1082/2013/EU: “Serious cross-border health threats and International Health Regulations”

The **IHR** require **Member States** to develop, strengthen and maintain their capacity

- to detect, assess, notify and respond to a public health emergency
- to promote interoperability between national preparedness planning



Source of pictures:
Website RKI <https://www.rki.de>



Risk and threats for PH emergencies:

- *Globalization and migration*
- *Endemic diseases*
- *Bioterrorism and Bioweapons*

Decision 1082/2013/EU – Instrument for implementation of IHR in Europe

***Integrated, coordinated and comprehensive approach for
preparedness, risk assessment and crisis response***

Article 4

Preparedness and response planning:

- sharing best practice and experience
- promoting the interoperability of national preparedness

Article 7

Ad hoc monitoring

Article 8

Establishment of an early warning and response system

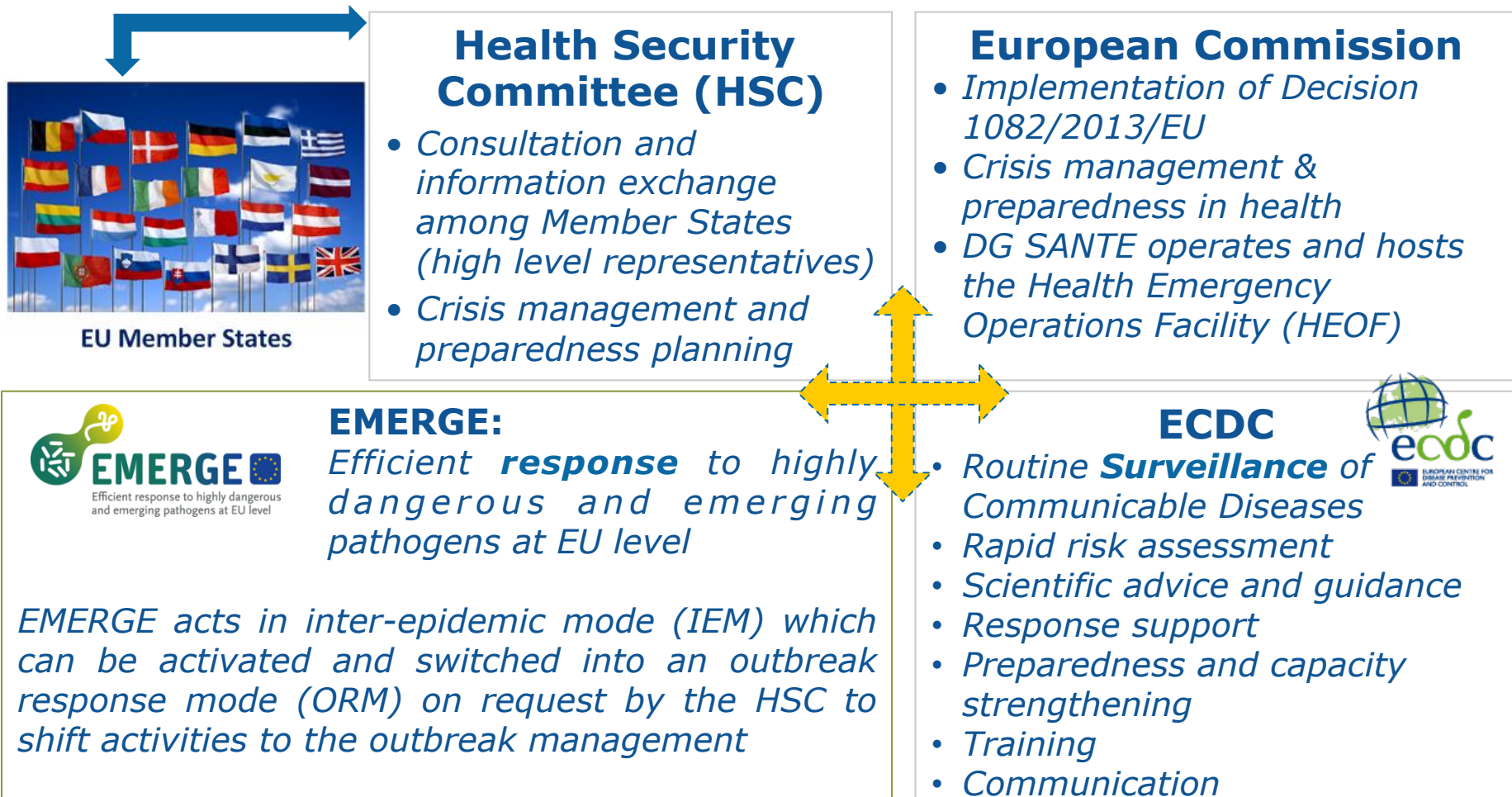
Article 9

Alert notification:

- the type and origin of the agent;
- the date and place of the incident or outbreak
- means of transmission or dissemination
- it is unusual or unexpected for the given place and time,
- it causes or may cause significant morbidity or mortality in humans
- it grows rapidly or may grow rapidly in scale,
- it exceeds or may exceed national response capacity;

**To be
supported by
laboratory
analytical data**

EU-Structures of cooperation under Decision 1082/13/EU on serious cross-border threats to health



General information

EMERGE is an EU funded Joint Action (*CHAFEA n° 677 066*),

Further development of two previously funded actions EQADeBa and QUANDHIP since 2008

ROBERT KOCH INSTITUT



Coordinator:

Robert Koch-Institut (RKI), Berlin, Germany

Contact persons: Roland Grunow / Daniela Jacob

Co-Coordinator:

L. Spallanzani National Institute for Infectious Diseases (INMI), Rome, Italy

Contact persons: Giuseppe Ippolito / Antonino Di Caro

Duration: 1st June 2015 – 31st May 2018 (3 years)

Total EU co-funding (60%): 3.5 Mio EUR

Estimated project costs: 5.8 Mio EUR

EMERGE

Partners

Coordinator: RKI, Germany (NIB+NIV)

Co-Coordinator: INMI, Italy (NIB+NIV)

Associated Partners:

AGES, Austria (NIB)
CODA-CERVA, Belgium (NIB)
NCIPD, Bulgaria (NIB)
HZJZ, Croatia (NIB)
SUJCHBO, Czech Rep. (NIB)
DTU, Denmark (NIB)
TA, Estonia (NIB)
THL, Finland (NIB)
INSERM, France (NIV)
DGA, France (NIB+NIV)
BwLM, Germany (NIB)
FLI, Germany (NIB+NIV)
UMR, Germany (NIV)
BNITM, Germany (NIV)
AUT, Greece (NIV)
NCE, Hungary (NIB+NIV)

ISS, Italy (NIB)
IZSLER, Italy (NIB)
NV SPL, Lithuania (NIB)
RIVM, Netherlands (NIB)
NIPH, Norway (NIB)
NVI, Norway (NIB)
NIPH-NIH, Poland (NIB)
NVRI, Poland (NIB)
INSA, Portugal (NIB+NIV)
INC, Romania (NIB)
UL-IMI, Slovenia (NIV)
BIOEF, Spain (NIB)
ISC III, Spain (NIB+NIV)
FoHM, Sweden (NIB+NIV)
PHE, United Kingdom (NIB+NIV)
EMC, Netherlands (NIV)

Collaborating Partners:

IZSPB, Italy (NIB)
NKUA, Greece (NIB)

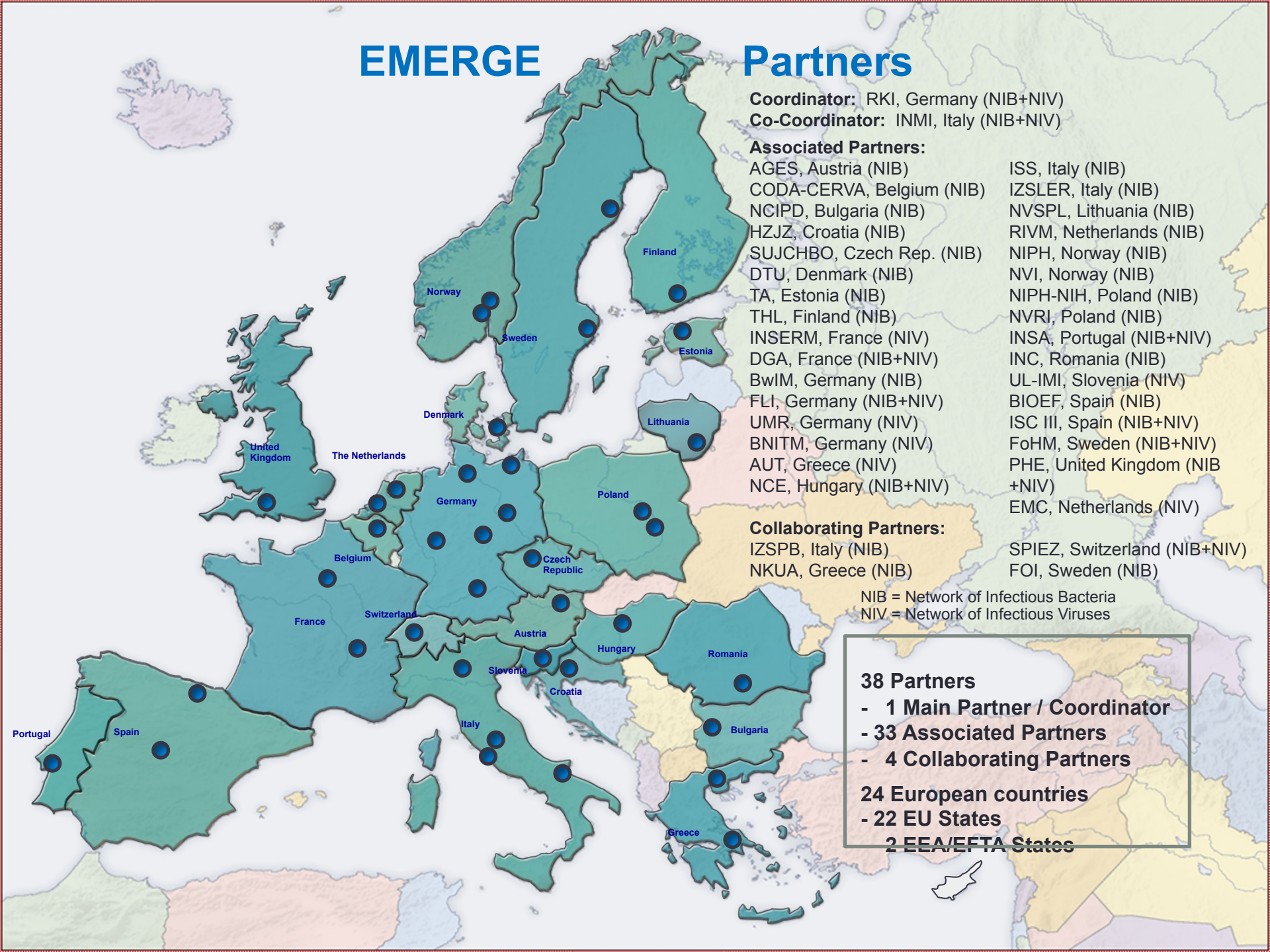
NIB = Network of Infectious Bacteria
NIV = Network of Infectious Viruses

38 Partners

- 1 Main Partner / Coordinator
- 33 Associated Partners
- 4 Collaborating Partners

24 European countries

- 22 EU States
- 2 EEA/EFTA States



Project Summary & General Tasks

European policy (Decision No 1082/2013/EU)

>>> There is a **need for an efficient, rapid and coordinated response to high threat pathogens** causing serious cross-border outbreaks. <<<

General Tasks

- To ensure an efficient **response** to serious **emergent and re-emergent cross-border events**.
- To contribute to a coordinated and effective response to such outbreaks by **linking up laboratory networks and institutions**.
- To perform **external quality assurance exercises** and give appropriate **trainings** and to ensure laboratory responsiveness, diagnostics and laboratory bio-risk management during outbreaks.
- 2 modes: a so-called **inter-epidemic mode (IEM)** and an **outbreak response mode (ORM)**.

Inter-epidemic Mode (IEM) and Outbreak Response Mode (ORM)

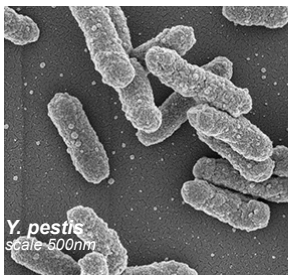
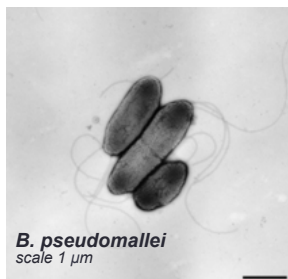
“Inter-Epidemic Mode” (IEM)

- work packages (WP) will be run for preparedness as agreed in the Grant Agreement

“Outbreak Response Mode” (ORM)

- work packages will be run in an **outbreak mode**
- specific tasks are defined for each WP
- modifications of the work plan
- budget changes and shifting

List of agents in focus



Bacteria	Viruses
<i>Bacillus anthracis</i>	Filoviruses (Ebola Hemorrhagic Fever)
<i>Francisella tularensis</i>	Arenaviruses (Lassa Hemorrhagic Fever)
<i>Yersinia pestis</i>	Bunyaviruses (Crim Congo Hemorrhagic Fever)
<i>Burkholderia mallei</i>	Orthopoxviruses (Monkey pox)
<i>Burkholderia pseudomallei</i>	Paramyxoviruses (like Nipah and Hendra viruses)
<i>Brucella</i> spp.	New viruses (Not yet identified)
<i>Coxiella burnetii</i>	

Working Groups

- **WG1 – Metagenomics** – 29 members

- Questioning of all partners to collect information about the used metagenomics approaches (*i.e. sample preparation, bioinformatic pipelines, NGS platforms*)
 - Usage of the EQAE to perform metagenomic assays
-

- **WG2 – RG4 Detection methods** – 15 members

- Neutralization and sample inactivation of risk group 4 viruses is the main topic
 - The development of a questionnaire to collect information on inactivation procedures available among partners is planned
 - Organization of neutralization tests (voluntary based) is in progress
-

- **WG3 – Antimicrobial Susceptibility Testing (AST)** – 16 members

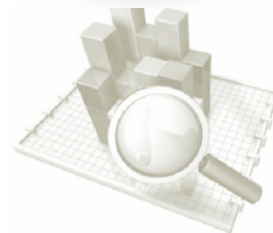
- Best laboratory practices to perform ASTs in a BSL3 containment and development of SOP – close discussion with EUCAST
- Based on “microdilution 96 well plates” (MERLIN) with given panels of antibiotics in appropriate concentrations, testing in EQAE

Three EQAE for bacteria and viruses (more experience together with previous projects >10 EQAE)

Steps and tasks (slight differences between EQAE)

- To assess the ability of participants to receive and process samples
- To monitor correct and timely shipment (31.2 ± 8.5 h; n=28)
- To analyze test items:
 - To **identify targets** in samples spiked with targets & **to rule out all targets** in samples spiked with non-targets
(i.e. Qualitative analysis for living and inactivated samples)
 - To **calculate the Genome Equivalent (GE)** of targets in samples
(i.e. Quantitative analysis for inactivated samples)
- To report preliminary results as fast as possible and final confirmed results (7.3 ± 6.6 h; n=26)

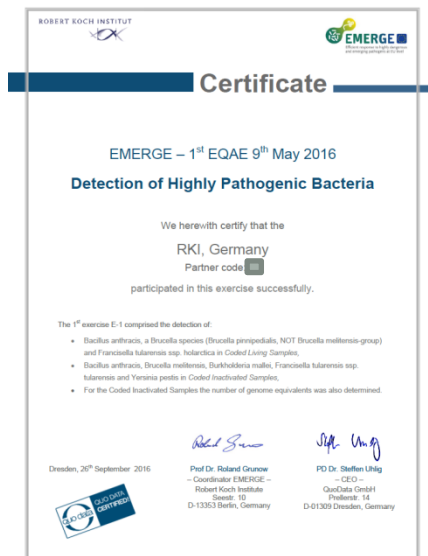
Improvement and consolidation over the period of time!



Summary of EQAE Results

Overall:

- **Most participating laboratories performed with a very high level of diagnostic quality**
- **Improvement could be seen over EQAE; but not always because challenges were increased**
- **Shipment time and border control were improved**
- **Identification of *Brucella* species and *Francisella tularensis* subspecies should be improved**
- **First trials on serology showed the importance to further include and therefore to respond to the request by participants**
- **Kits might miss specific variants in viral genomes (Lassa Nigeria)**
- **Quantification is still a problem – different methods, different reference standards**



**Recently accreditation
as Proficiency Test
Provider according
DIN EN ISO 17043**



Key Points

- **Living European network on risk group 3 bacteria and risk group 4 viruses**
- Support of **IHR** by providing laboratory capacities and capabilities
- Laboratory **preparedness** and **responsiveness**
- **Interoperability** between laboratories in different MS as well as with other networks and agencies
- **External Quality Assurance Exercises** and **reference material**
- Validation and improvement of **biorisk management**
- **Training** on laboratory management

New JA 2018/2019 based on EMERGE



IHR Implementation

Third Programme for the European Union's action in the field of health (2014-2020) —
Work Programme for 2018

Annex 2, 2.2. Joint Actions

2.2.1. Joint Action to strengthen preparedness in the EU against serious cross-border threats to health and support the implementation of International Health Regulations (IHR)

Two general parts: The Joint Action will help

- strengthen preparedness including laboratory capacities
- and the implementation of IHR in the EU.

Expected activities under the new Joint Action

1.) **Strengthen preparedness and the implementation of IHR,**

- improving cross-sectoral preparedness and response capacity in Member States by different measures,
- sharing best practices or lessons learnt from response to recent outbreaks
- and others...

2.) **Strengthen laboratory preparedness in Member States**

- to develop their capacities to detect, investigate and report potential cross-border threats...such as disease outbreaks
- to improve laboratory services capable of producing reliable results in a timely manner
- to maintain the **network of European microbiology laboratories for highly pathogenic agents**
- to conduct **External Quality Assessments** for highly pathogenic agents and to provide **practical training** to staff.

Acknowledgement

- EC DG SANTE and Chafea
- all partners of the Joint Action
- Staff ZBS 2 and RKI



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Search term

EMERGE 
Efficient response to highly dangerous
and emerging pathogens at EU level

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EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level

The human population is confronted with emerging and re-emerging infectious pathogens with the potential to cause serious cross-border outbreaks. A recent example is the Ebola outbreak requiring strong diagnostic, clinical, and public health measures in Europe and abroad in order to get this incident under control.

The Joint Action EMERGE comprises a European network with about 40 diagnostic laboratories focused on risk group 3 bacteria and risk groups 3 and 4 viruses. EMERGE aims to provide a common, coordinated and efficient response to infectious disease outbreaks at EU level and abroad.

State of the art and new diagnostic methods for high threat pathogens are evaluated. External quality assurance exercises and training schemes are performed to ensure best approaches for laboratory response in outbreak situations.

Date: 04.11.2016



NEWS

LAUSA Fever
A brief instruction for handling and transport of samples from suspected cases and exposed contacts, including referral for diagnostic confirmation (EMERGE Network, Work Package 5)

Integrated European Checklist for Laboratory Biorisk Management (ECL-Biorisk)
The Integrated European Checklist for Laboratory Biorisk Management in Handling of High Consequence Risk Group 3 and 4 Agents (ECL-Biorisk) can be used as a tool for self-evaluation to assess current biorisk management systems.

Co-funded by the Health Programme of the European Union

EMERGE partners in front of the Robert Koch Institute

Please download
EMERGE-flyer (PDF, 200 KB, Not barrier-free file.)

Print

Website : <http://www.emerge.rki.eu>