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Efficient response to highly dangerous and emerging pathogens at EU level

**JA2015 - GPSD [705038]**

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Project abstract

The human population is confronted with emerging and re-emerging infectious pathogens that can 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 JA EMERGE is in compliance with the European policy (Decision No 1082/2013/EU) where the need for an efficient, rapid and coordinated response to high threat pathogens is defined. The JA EMERGE comprises a European network with more than 40 diagnostic laboratories focused on risk group 3 bacteria and risk groups 3 and 4 viruses. It will act in a so-called inter-epidemic mode (IEM) which can be activated and switched into an outbreak response mode (ORM) on request by the Health Security Committee in order to direct all activities to the outbreak management. A number of other laboratory networks, institutions and agencies are contributing to the management of cross-border infectious outbreaks. EMERGE will provide a platform for establishment and consolidation of a common, coordinated and effective response to infectious disease outbreaks at EU level and abroad (WP4). State of the art and new diagnostic methods for high threat pathogens, including in-house and commercial kits, will be evaluated for their applicability and recommended in outbreak situations when suitable (WP5). External quality assurance exercises will ensure best approaches for laboratory responsiveness in outbreak situations (WP6). These activities must be supported by an appropriate training to share best practices of diagnostics and bio-risk management (WP7). In conclusion, the general objective will be to ensure efficient response to serious emergent and re-emergent cross-border events by reinforcing the existing EU network of BSL 3 and BSL 4 laboratories which are already active in the field of identification of dangerous bacterial and viral human pathogens.

Summary of context, overall objectives, strategic, relevance and contribution of the action

The human population is confronted with emerging and re-emerging infectious pathogens that can 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 JA EMERGE is in compliance with the European policy (Decision No 1082/2013/EU) where the need for an efficient, rapid and coordinated response to high threat pathogens is defined. The JA EMERGE comprises a European network with about 40 diagnostic laboratories focused on Risk Group (RG) 3 bacteria and RG 3 and 4 viruses. It is acting in a so-called inter-epidemic mode (IEM) which can be activated and switched into an outbreak response mode (ORM) on request by the Health Security Committee in order to direct all activities to the outbreak management. Other laboratory networks, institutions and agencies are contributing to the management of cross-border infectious outbreaks. EMERGE will provide a platform for establishment and consolidation of a common, coordinated and effective response to infectious disease outbreaks at EU level and abroad (WP4). State of the art and new diagnostic methods for high threat pathogens, including in-house and commercial kits, will be evaluated for their applicability and recommended in outbreak situations when suitable (WP5). External quality assurance exercises will ensure best approaches for laboratory responsiveness in outbreak situations (WP6). These activities must be supported by an appropriate training to share best practices of diagnostics and bio-risk management (WP7). In conclusion, the general objective will be to ensure efficient response to serious emergent and re-emergent cross-border events by reinforcing the existing EU network of BSL 3 and BSL 4 laboratories which are already active in the field of identification of dangerous bacterial and viral human pathogens.
networks (e.g. the EVD-LabNet), institutions and agencies are also contributing to the management of cross-border infectious outbreaks. EMERGE is providing a platform for establishment and consolidation of a common, coordinated and effective response to infectious disease outbreaks at EU level and abroad. State of the art and new diagnostic methods for high threat pathogens, including in-house and commercial kits, are evaluated for their applicability and recommended in outbreak situations when suitable. External quality assurance exercises (EQAEs) ensure best approaches for laboratory responsiveness in outbreak situations. These activities must be supported by an appropriate training to share best practices of diagnostics and bio-risk management. In conclusion, the general objective is to ensure efficient response to serious emergent and re-emergent cross-border events by reinforcing the existing EU network of BSL 3 and BSL 4 laboratories which are already active in the field of identification of dangerous bacterial and viral human pathogens.

Methods and means

The horizontal Work Packages (WPs) comprise Coordination, Dissemination, and Evaluation of the Joint Action (JA) ensuring the implementation of the project as planned and budgeted. A pro-active visibility is provided to laboratory staff and first line health professional responders in case of outbreaks. In addition, the scientific community, public health experts and politicians are provided with information on the progress of the JA by the regularly published newsletters, presentations held during conferences, publications in journals and further appropriate dissemination channels like personal contacts and direct approaching of stakeholders. All WPs are designed to pursue their specific objectives in an interepidemic mode (IEM) and in an outbreak response mode (ORM). Upon activation by the Health Security Committee (HSC), the coordinator ensures the switch from IEM to ORM which has not been the case during the first and second reporting period (June 2015 - May 2017). Together with the Steering Committee (SC), an ORM Working Group (WG) was established. The ORM WG is meant to cope with outbreak management during ORM. A continuous evaluation assesses whether the right and relevant information is distributed and the right target groups are approached.

Work performed during the reporting period

A short summary outlining the work performed during the 2nd reporting period is given below - detailed descriptions are part of the report.
During the 2nd reporting period, the first periodic report was delivered as scheduled in the Grant Agreement, 31 July 2016. The Consortium Agreement was signed by all partners of the JA, except for the new Romanian partner (INC). EMERGE is usually and currently directed to work on preparedness and planning of outbreak management, defined as interepidemic mode (IEM). In case of an outbreak, coordinator and co-coordinator will ensure the reliable activation of the network, i.e. the switchover from IEM to ORM (outbreak response mode), supported by the Steering Committee (SC). A plan for transition from IEM to ORM was developed and approved by the SC. The second EMERGE meeting took place in Thessaloniki in October 2016.

For external communications of activities different means are used comprising the EMERGE website, newsletters, flyer and presentations at conferences. A 2nd newsletter was prepared and published; the 3rd newsletter is in preparation.

Evaluation reports for progress of achieved Milestones and Deliverables were generated in January 2016 and April 2016, a presentation on progress was delivered in September 2016 and a report generated in March 2017. The technical meeting in Berlin and the 2nd project meeting in Thessaloniki were evaluated with a questionnaire to ascertain the quality and impact of the meetings. A report was generated for each of the evaluations highlighting the areas of success as well as areas for improvement.

The report on the inventory of EU funded projects and networks which enables identification of areas for collaboration was further completed and finalized. The report includes a short description of networks and EU funded projects with activities that could be involved in the response management of cross-border health threats. The focus is primarily on provision of laboratory support, which can be quite diverse, given the diversity of cross-border threats that are potentially involved. A publication of survey B presenting the data and conclusions was drafted and submitted to Eurosurveillance and is currently under review. The survey A report has been drafted and will be submitted for publication in the beginning of period 3. An outbreak scenario was provided, using six sessions of information. The scenarios were used on 30 November 2016 at an Outbreak, Preparedness and Response Coordinators meeting, organized in Amsterdam, to gain insight in the extent to which information is exchanged among the attending networks and organizations.

For the Assessment of target pathogens of the next project year, WP5 leader INMI disseminated different questionnaires among all partners with the aim of:
1. Setting up the list of agents on which to perform the activities for the second year of the project (i.e. EQAEs)
2. sharing the survey on "criteria selection" with all partners (the previous one was disseminated only among the SC) to assign a score to each agent and eventually redefine the pathogens with highest score (as decided during the meeting in Thessaloniki)
3. verifying the availability of human samples to perform Ab detection in order to implement serology of agents relevant for our project
4. implementation of new diagnostic tests for pathogens with cross-border potential

Besides, a second survey has been circulated among partners to assess the benefits of EMERGE for the partner laboratories.

All participants of the first bacterial and viral EQAEs received certificates evaluating their performance. Further, individual and overall results were discussed during the 2nd EMERGE meeting in Thessaloniki, October 2016. The second round of EQAEs was already performed, results are under evaluation. Training needs and offers were identified and the training programme has started. Evaluation (post course assessment) of the trainings is continuously implemented by mea.

The main output achieved so far and their potential impact and use by target group (including benefits)

The network of partner laboratories comprises public health laboratories, veterinary laboratories, and military laboratories. These laboratories represent the main target groups. Target groups are also informed through the website, the EMERGE leaflet, a bi-annual newsletter, presentations on scientific and public health conferences, further specifically organized meetings with relevant networks, and personal exchange. Additionally, other relevant networks were contacted for possible cooperation during the Outbreak, Preparedness and Response Coordinators meeting in Amsterdam. The involved network coordinators are, now, better informed of activities already existing in other networks. Duplications can be avoided and the opportunity to compare results and procedures with other European (ERINHA-2) and non-European infrastructures/networks (GHSAG) is provided.

The EMERGE activities and outcomes have shown that the JA is having a positive long-term effect on the performed quality of diagnostic laboratories. EQAEs and training served to improve the potential for responsiveness of the partner laboratories in outbreak situations. The EQAE certificates were used by partner laboratories for accreditation purposes. The JA can already now ensure the interoperability between the partner laboratories and other institutions (e.g. D4.1 and MS16) and when it comes to the diagnostics of highly pathogenic bacteria and viruses.

As a matter of fact, single Member States would not be able to develop a coordinated European preparedness and readiness to respond to pathogens naturally spreading across political borders. Moreover, the EMERGE network is not just the sum of the participating laboratories but considerably benefits from the generated synergies among the partners, as could be shown by the results of the recently conducted survey (as attached to the report).
Achieved outcomes compared to the expected outcomes

A strategic, long-lasting vision, able to merge and optimize existing resources and capabilities and to create new knowledge, is necessary to support Europe in the event of severe cross-border epidemics. In many countries considerable gaps still exist and several issues are unresolved to support evidence-based clinical guidelines, and patient management protocols. Effective transnational preparedness and response requires the setting-up of cooperative relationships prior to an event, regardless of the origin or type of the potential infectious disease threat. The EMERGE JA has the potential to deliver these impacts by taking advantage of its extraordinary capability to mobilize European and international resources, its partners’ longstanding experience in coordinating such disparate efforts, and by their high and recognized level of scientific expertise. The dissemination of results of the project activities such as meeting reports, exercise reports and approved procedures will be discussed during periodical meetings, taking into account issues such as the sensitivity of the content of reports.

The main expected outcomes are outlined below:

• Production of protocols and/or guidelines by the interaction of relevant networks or agencies, including ECDC, for outbreak management based on the continuous assessment of emerging and re-emerging infectious pathogens that have a potential to cause cross-border outbreaks (IEM) and supporting the interoperability of networks (WP4) and development of specific recommendations for diagnostic approaches in close interaction with WP5-7 (ORM).

• Increase of diagnostic capabilities for high treat pathogens (during IEM) and application of best practice approaches for diagnostics in outbreak situations, especially supporting Member States without the required laboratory capacities/capabilities (during ORM) (WP5).

• Assessment of status quo and recommendations for improvement and maintenance of laboratory capabilities and the high quality for diagnosis of highly pathogenic viral and bacterial agents, and for the diagnosis of pathogens in “unknown” samples in an inter-laboratory approach by EQAEs (IEM) and establishment of quality assurances of diagnostics in cross-border infectious outbreaks (ORM), provision of reference material in case of both modes (WP6).

--> 4 EQAEs were carried (2 viral EQAEs and 2 bacterial EQAEs). The identified diagnostic gaps and ways of improvement were addressed during 2 specific meetings (for the viral part in Rome, for the bacterial part in Berlin) and one general meeting in Thessaloniki. Certificates on the performance were dispatched to all participants for the first round of
EQAEs.

- Validation and improvement of biorisk management in partner laboratory (IEM) and beyond (ORM) (WP6).
- Application of the Biorisk Management in Handling of High Consequence Risk Group 3 and 4 Agents (ECL-Biorisk) developed during the previous JA QUANDHIP – identification of gaps □ Training on Biosafety & Biosecurity, e.g. provided by the RKI.
- Identification of synergies between the existing repositories of reference strains of the JA and different providers of appropriate reference material on highly pathogenic agents of risk group 3 and 4 (WP6).
- This process is ongoing, further usages of the reference material needs to be discussed and will be under legal consideration.
- Improvement of the European capability to detect highly pathogenic agents by training (IEM) and application of ad-hoc training directed to outbreak causing highly pathogenic agents (ORM) (WP7).
- A training programme based on identified needs has been developed. It includes 16 training courses within the four specified areas: biorisk management, laboratory methods, diagnostic algorithms and field diagnostic laboratory methods. So far, 13 courses provided by six partners were held for a total of 46 trainees.

For the second reporting period, it was foreseen to provide eight deliverables

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Dissemination and evaluation activities carried out so far and their major results

Listed in the following section are the dissemination activities carried out and presented at various events during the first and second reporting period of the JA EMERGE:

- 10-06-2015 VIROGENESIS meeting in Leuven, Belgium
- 18/19-06-2015 EDUFLUVAC workshop in London, United Kingdom
- 22-06-2015 PREPARE meeting in Antwerp, Belgium
- 08-09-2015 COMPARE meeting at Schiphol, The Netherlands
- 09-09-2015 PREPARE meeting in Antwerp, Belgium
- 23/24-09-2015 COMPARE meeting in London, United Kingdom
- 28-09-2015 PATHSEEK meeting in Rotterdam, The Netherlands
- 12 to 14-10-2015 Ebola meeting, EMERGE presentation, Luxembourg (Giuseppe Ippolito)
- 18/19-11-2015 ECDC expert consultation on ECDC strategy on WGS in Stockholm, Sweden
- 25/27-11-2015 ANTIGONE/PREDEMICS meeting in Rotterdam, The Netherlands
- 30-11 to 02-12-2015 WHO consultation on Anticipating Epidemics in Geneva, Switzerland
- 10/11-12-2015 WHO consultation on MERS R&D, development of a global
MERS R&D roadmap in Geneva, Switzerland

- 20-01-2016 COMPARE meeting in Copenhagen, Denmark
- 2/2016 Presentation and discussion of EMERGE evaluation of the European Ebola labs in Africa, Senegal
- 01-02-2016 RKI News, presentation JA EMERGE
- 03/2016 three-day ECCMID Arbo-virus course in Thessaloniki, Greece
- 08/10-03-2016 COMPARE meeting in Copenhagen, Denmark
- 22/23-03-2016 Conference on Global Health Security, Lyon, France
- 09 to 12-04-2016 ECCMID 2016, Amsterdam, The Netherlands (Carla Nisii)
- 20 to 22-04-2016 PREPARE meeting Madrid, Spain
- 25/26-04-2016 EVAg meeting in Rotterdam, The Netherlands
- 26 to 29-04-2016 15th Medical Biodefense Conference, Munich, Germany
- 10-05-2016 Livestock Forum in Barcelona, Spain
- 13/14-05-2016 EVDLabNet meeting in Stockholm, Sweden
- 08/09-11-2016 28th GHSAG-LN meeting, Winnipeg, Manitoba, Canada
- 30-11-2016 Outbreak Preparedness and Response Coordinators meeting, Amsterdam, The Netherlands
- 14/16-02-2017 ECDC Expert consultation on ranking and prioritizing EIDT for preparedness, Stockholm, Sweden
- 15-03-2017 Final meeting of PANDEM project, Brussels, Belgium
- 05/07-04-2017 Ebola MoDRAD 3rd workshop on outbreak management, Porton Down, United Kingdom
- 10-05-2017 ERINHA workshop for the scientific community and potential users, Brussels, Belgium

Representation of EMERGE by peer-reviewed journal articles:


Work package

Work Package 1: Coordination of the Joint Action
Start month: 1
End month: 36
Work Package Leader: RKI

Task 1 Implementation of the JA: The coordinator RKI represents the network and its interests at EU and international level. The action management will provide a systematic, interactive and correcting (if required) monitoring of activities to ensure the achievement of results and deliverables considering the timeline including milestones on high quality level. The coordination and co-coordination (INMI) will closely work together at the technical and managerial level, including periodical meetings and consultations, planning and evaluation, in collaboration with the other horizontal work packages. The coordinator, together with the co-coordinator INMI, and in collaboration with the Steering committee (SC), provides the expertise on laboratory management of infectious agents caused by highly pathogenic bacteria and viruses and ensures the implementation of the activities, as planned and budgeted. In case of specific actions related to bacterial or viral pathogens, the coordinator and co-coordinator act together but the lead will be assigned according to the required expertise on viruses or bacteria, respectively. In addition, the coordination will involve and request support from the members of the Steering committee and all other partners, if required. Therefore, a close and frequent contact between coordinator, SC, Chafea, and DG SANTE should be ensured on a monthly basis (or as it will be decided by the SC) to allow the continuous flow of information and the timely identification of gaps and countermeasures. ECDC participates as consultants to the EMERGE Steering committee in IEM. ECDC will participate in the outbreak response working group in ORM with one representative, following the EMERGE coordinator request. A web-based secure tele-conference system could simplify the communication, exchange of documents and even the online development of documents. Alternative approaches could also be used, if appropriate. In emergency cases when the ORM will be activated by the HSC and DG SANTE, ad-hoc meetings could be performed on short notice without additional travel costs and time loss. Furthermore, the SC will meet face-to-face at the regular meetings of the network. These meetings will be conducted jointly for both, bacterial and viral part of the network, at one location with common and separate sessions being organized: All in all, one kick-off meeting of the Steering committee in addition of 4 general meetings (1 kick-off meeting, 2 regular meetings and 1 final conference) of the whole consortium, including associated and collaborating partners as well as representatives of the EC services and the Advisory Board, will be organized. These meetings will also be used for face-to-face meetings of the SC and meeting with the Advisory Board. One additional work meeting on the preparation of EQAEs will be planned between two general meetings.

Further responsibilities of the coordinator:
• Act as the intermediary for all communication between the beneficiaries and the
Work Package 2: Dissemination of the Joint Action activities

Start month: 1
End month: 36
Work Package Leader: INSERM

A specific and appropriate dissemination strategy ensuring a pro-active visibility and on-time information about the JA will be developed. This strategy will comprise in particular:

Task 1 Development of the project’s communication infrastructure (M1-M36):
Internal communication between partners will be promoted by implementing a private secured collaborative portal, with member-restricted access through individual login and password. This section will facilitate aid and increase the transparency of the communication of partners within the consortium. It will display confidential information to be shared through the consortium, information about activities and will allow partners to upload documents to be shared with the partners.

External project communication tools
(1) Specific free accessible public Website will be developed and maintained to ensure smooth communication on JA EMERGE activities and progress, including communication on training sessions to be organised. Links to other websites/portals of the broader community, particularly the networks that are considered primary partners during response situations will be implemented.
(2) Publication and pro-active diffusion of bi-annual newsletters on JA EMERGE results

Task 2: Dissemination tools and activities (M1-M36):
(1) Development of harmonised and shared communication tools in order to define the “JA EMERGE’s corporate identity” (logo, leaflet, templates to be used for
presentations, reports, poster etc). Dissemination toolkit will be provided to all partners through the internal portal to allow us easy access and use the material for all project-related communication and dissemination regarding different work packages.

(2) Presentations and publications (at least 5).
- Presentations at national and international conferences, seminars and symposia,
- Publishing peer-reviewed scientific journals.
All principal investigators will strive to publish their results in open-access journals (Gold model). In case publications in open-access journals are not feasible, the publications will be made available via the website, respecting any embargo periods of the journal (Green-model). During outbreak situations (ORM), all partners will agree to rapid data sharing for outbreak support, and not withhold essential information for instance for publication reasons. In order to protect such academic needs, a secure data sharing environment will be used to discuss essential findings during outbreak situations, in order to produce guidance that may be of use for other parties.

In ORM the dissemination tools will be adapted as short term newsletters, direct approach of NFP, stakeholders, involved laboratories, other networks, etc.

Task 3 Development and maintenance of a user-stakeholder database (M1-M36): An up-to-date contact database of key organizations and contact persons to be informed regularly by JA EMERGE on its activities, its results and the added value thereof for these organizations and persons will be created and maintained. These stakeholders will encompass the organizations as represented in WP4 as well as routine clinical and public health laboratories, clinicians, epidemiologists, and policy makers in Europe including relevant DGs and agencies like ECDC, and beyond.

Work Package 3: Evaluation of the Joint Action

Start month: 1
End month: 36
Work Package Leader: PHE

Task 1 Evaluation of the management structure: This work package will ensure the timely and efficient completion of work packages across the entire project by providing a suitable reporting framework. The work package progress will be reviewed regularly internally and externally to ensure objectives are being achieved. All WP leaders and partners will provide required data for the evaluation. A steering committee (SC) will be established comprising all WP leaders and co-leaders. This SC will be responsible for the oversight of the project on a regular basis.

An external advisory board will also be established to give independent expert scientific input into this project to ensure the delivery in a timely and scientific robust way. Proposed members of the advisory board will be drawn from: DG SANTE, Chafea, other DGs, ECDC, and international partners who should reflect scientific, public health, political and security interests. Individual persons will be asked for their participation. The external advisory board will contribute advice and guidance to this WP.

Task 2 Monitoring of the implementation of the project: At the start of the project
we will determine the baseline capability of each work package within the network: Each WP will present a 1 page summary of the status of their respective WP within the network at the start of the project to the evaluation lead - WP3. An evaluation strategy will be agreed with the steering committee at the start of the project to establish the measures of project success and these will also be agreed with the external advisory board before the project uses these metrics. This will ensure the external advisory board and project members have the same targets for project success from the outset.
Continuous evaluation of all WP activities will be achieved by several methods. The interim and final reports will be evaluated before submission.
Progress / situation reports will be compiled for each work package biannually or after each project meeting as agreed during the evaluation strategy with WP leads. Mandatory questionnaires will also be evaluated after each meeting. These progress reports / SITREPS will be compiled and will include a description of the work that has been undertaken in the reporting phase and an assessment of whether it has been effectively completed using the scoring metrics agreed including a Red Amber Green (RAG) status (if adopted) and evaluated by members of the Advisory board. Information from the Advisory board will be fed back into the network at meeting updates any critical information requiring immediate notification will be disseminated to the network via e-mail.
For each EQA panel, results and feedback will be compiled from each partner laboratory and submitted to the coordinator after each EQA has been delivered to partner laboratories (after a mutually acceptable period). Reports will include details of the overall precision of results for each EQAE in each laboratory including the range of detection technologies used and response capabilities. In the first year we expect this information to guide decisions and progress in the training work package regarding new or bespoke training activity in assay systems which will enable further evaluation with EQA testing and additional rounds of appraisal. In this way the project will focus on the development of harmonized adoption of best practice and gold-standard assay systems across the network.
Reports on WP3 progress will be supplied to the co-ordinator for inclusion in mandatory deliverables of WP1 at 18 months and 36 months.
In ORM, Evaluation will continue to be applied if outbreak response mode is activated to ensure the success of this mode. The short term evaluation of dissemination of information and recommendations to laboratories and stakeholders and of activities in other WP will ensure the adequate response of the JA EMERGE in outbreak situation and, if necessary, recommend approaches for improvement.

Work Package 4: Networking of networks for laboratory response
Start month: 1
End month: 36
Work Package Leader: EMC

IEM
Task 1: Scanning of emergent and re-emergent health threats: To assess whether
there is a need for updates in laboratory protocols for new (emergent and re-emergent) pathogens. The basis will be search of scientific and public health literature and information, ECDC risk assessments (MoU will be developed), signals from the laboratory networks. Signals will be listed and discussed with the other WP leaders to prioritize. If the need for an update is identified, this will be discussed with the network of networks in order to avoid duplication and coordinate activities (Task 2).

Task 2 Identification of key laboratories: To identify key partners in development of seamless laboratory preparedness and response across the tiers of the laboratory system in Europe (clinical, public health, and specialized high containment laboratories). This group will form the core network of networks, that will be the partners for developing the laboratory preparedness for and during outbreaks. To identify key laboratory information, expertise, and capacity required for optimal preparedness and response to high threat pathogens for clinical, public health and high containment reference laboratories, in close collaboration with the network of networks.

The activities of this WP will require a strong commitment from the EC and participants for the identification and the involvement of relevant contacts from other networks and projects, such as the European Mobile Laboratory, the Influenza networks, ENIVD, ShipSan, AIRSAN, EpiSouth-Plus, ERINHA, EVA, VBORNET, GV Network, EPIZONE, ANTIGONE, PREDEMICS, COMPARE and PREPARE, and others. In addition, liaison with WHO-led activities will be explored. For this, a round of (telephone) interviews will be done to understand the role and ambitions of the different networks in laboratory preparedness and response, and the expertise they can provide. This information will be summarized in a brief report, and conclude with a proposed list of key partners.

Task 2.1 A contact list will be drafted of coordinators and a lead scientist from the selected networks. At EMERGE, a working group will be set up consisting of the WP4 leader as the core element and the other WP leaders in support to this activity. These will be convened for a kick-off meeting, to explain the network functions to the other participants, and to discuss collaboration during IEM and ORM. For this, an outbreak response protocol will be discussed, explaining the need for rapid exchange of information in case of outbreaks, in order to discuss ways to facilitate this. Based on this workshop, a protocol for interaction during outbreaks will be prepared. It is planned that the group will meet overall 6 times (face-to-face and teleconference), to discuss topics relevant to the development of the network collaborations including identification of gaps and overlaps, and on lessons learned from previous outbreaks. The program for the first year will be the evaluation of the Ebola response as described in task 2.2. Items for further work in the following period will be identified by consultation of the network, EMERGE partners, and the European commission. When gaps are identified, development and validation of protocols will be supported for laboratory support to treatment of patients with high threat pathogens, for use in specialized hospital laboratories with BSL2 and BSL3 containment facilities. In between face to face meetings, TCs will be organised with the network of networks partners during IEM. During ORM, at least one rapid TC consultation will be done as described under task 4.

Task 2.2. Evaluation of lessons learned for laboratory preparedness: Following each outbreak in which the EMERGE partners are involved, an evaluation will be done to assess key laboratory information, expertise, and capacity required for optimal
preparedness and response to a large outbreak caused by a high threat pathogen. In these evaluations, the network part

**Work Package 5: Rapid capabilities for diagnoses**

Start month: 1  
End month: 36  
Work Package Leader: INMI

Specific sessions dedicated to the different diagnostic approaches for RG3 and 4 pathogens employed by laboratories that are partners of the project or belonging to other relevant European networks for RG3 pathogens will be organized in the framework of the general meetings and a strategy to share methods, reagents and samples will be developed to support the implementation in all participating MS of a wide panel of diagnostic methods. The relevant target pathogens will be identified together with WP4. The identified best methods and practices will be considered in WP6 on EQAE and WP7 on training. Methods developed by relevant European research projects will be discussed in the project meetings and submitted to evaluation if appropriate.

**IEM**

**Task 1 Specific diagnostics/Working Groups:** Working groups will be dedicated to specific aspects of the diagnosis of pathogens, including rapid sharing of reference materials necessary for outbreak assessment and response. The European capacity/capability for rapid identification and confirmation of laboratory results will be strengthened through evaluation or development of new methods, as well as establishing routines for rapid sample sharing in case of outbreak. These activities, incl. Working Group meeting, will be undertaken by partner laboratories and in collaboration with other networks or relevant EU-funded projects involved in surveillance and preparedness (e.g. ENIVD, ERINHA, EMLab, MEDLAB SECURE, HOME/Security and DEVCO programmes) as well other organisations, EU institutions (ECDC Microbiology network and EUPHEM programme, GHSAG lab network) and international actors. Formal agreements with these Networks will be established in the framework of WP4. Relevant new information on diagnostic issues will also be shared through links with the other networks.

**Working Groups (IEM):**
1) Metagenomics approach for known and ‘unknown’ agents detection: Joint, bacteria and viruses. The main focus of this working group should be standardization of procedures and collaboration with COMPARE (INSERM)
2) RG4 pathogens detection and characterization methods to be applied in BSL4 such as virus isolation, virus neutralization and standardization of basic diagnostic techniques and BSL3 laboratories (including glove box) where BSL4 are not available (BNI)
3) Antimicrobial susceptibility testing (AST) of highly pathogenic bacteria; development of standard operational procedures, determination of break points. The outcomes will be provided to and discussed with EUCAST.

**ORM**
Task 2 Support to Member States with low capacities and capabilities: WP5 will support Member States, and especially those that do not have, or have only limited, diagnostic BSL3/BSL4 laboratory capacity for diagnosing highly pathogenic, outbreak-prone emerging agents or new infectious agents. Ad-hoc advice on diagnostic test kits and approaches as well as exchange of methods and reagents (including reference material) will be provided. In the framework of agreement developed in WP4, activities will be carried out in collaboration with public health and epidemiological networks/authorities. In the consortium agreement that will be agreed and drafted under WP1 each partner will be asked to declare their availability to provide support in case of outbreak response.

Task 3 Collaboration with other networks: Key to this WP will also be the collaboration with the European Mobile Laboratory and other networks to improve outbreak response capacity outside of the EU (see description and justification under WP4).

Work Package 6: Quality assurance of laboratory diagnostics
Start month: 1
End month: 36
Work Package Leader: RKI

External Quality Assurance Exercises (EQAEs) on highly infectious merging and re-emerging pathogens are essential for the preparedness, maintenance and improvement of the labs’ diagnostic activity. There are no comparable national schemes for risk group 3 bacteria and risk group 4 viruses in EU Member States. In addition, due to our knowledge, some elements of comparable commercial EQAE might exist, but they are mainly restricted to evaluation of methods by using RNA or DNA of pathogens and does not reflect the whole diagnostic approach and the possible complexity of samples. Therefore the continuation of European EQAEs will lead to a consolidation and further improvement of diagnostic capabilities of all MS participating in the new JA. Laboratory preparedness for the diagnosis of highly pathogenic agents and management of a real outbreak situation should be the main target of EQAEs. The target agents of risk group 3 and 4 pathogens causing emergent and re-emergent infectious diseases will be defined for EAQE by risk assessments performed in framework of WP4. The outcomes of the EQAEs including the biorisk management will have a direct impact on WP5 new diagnostic approaches and WP6 for identifying of training needs. In addition, regulations on maintenance and usage of existing repositories will be developed and synergies with other bio-banks identified.

IEM
Task 1 EQAE:
EQAEs will be directed to (re-)emerging viral and bacterial pathogens identified under WP4. Upcoming EQAEs should reflect real diagnostic issues: for example unknown samples provided as spiked blood / serum samples with basic information comprising clinical presentation. New tasks like antibody detection should also become part of these EQAE.
There are two separate EQAEs planned, one per a year, for bacteria and viruses, and one common EQAE for both agents as a final exercise. The final common EQAE comprises for risk group 4 viruses inactivated material only. The idea of the common exercise besides the correct diagnostics is how the labs proceed with viral or bacterial samples which they cannot identify.
The EQAE samples may comprise living and/or inactivated samples as well as serological samples for antibody detection.

In order to foster and support the multi-competence perspective to diagnostic challenges for high consequence pathogens, the outcomes of the planned Working Groups (WG) under WP5 could be implemented here in EQAE WP6 and could be trained under WP7. As an example, in the framework of the bacterial EQAEs, Antimicrobial Susceptibility Testing (AST) should be carried out using the Standard Operation Procedures (SOP) for further evaluation, developed so far. The results will be provided to and discussed with EUCAST, as this committee was already involved in the initial activities of AST in framework of QUANDHIP and expressed great interest in these developments.

For the planning and evaluation of the EQAE results, a professional statistics agency will be appointed in order to obtain comparable outcomes. The EQAE will also consider the appropriate reporting applicable in real scenarios to the sender of samples (clinicians, public health agencies). The EQAE reports should identify what are the diagnostic gaps and propose specific recommendations for improvement of methods, training for laboratory personnel, etc.

Task 2 Implementation of biorisk management check lists: The implementation of the biorisk management check list generated during the QUANDHIP JA, should be used for validation of the BSL3/4 labs/work of participant’s in EQAE and especially of new participants not yet validated or for new constructed labs of participants in this JA before sending EQAEs.

Task 3 Development of rules for maintenance, further development and usage of repositories: A further activity is to consolidate the bio-diverse repositories on risk group 3 bacteria and risk group 4 viruses with potential ability to cause cross-border outbreaks and represent

Work Package 7: Training on diagnostics and biorisk management
Start month: 1
End month: 36
Work Package Leader: FoHM

This work package will support practical and theoretical training for partners of the JA in order to develop a standard capability in (a) diagnostic algorithms, (b) laboratory methods (c) biorisk management and (d) field support. Training will be based on the needs of participants based on the self-evaluation of partners and
based on the activities in WP5 and WP6.

IEM

Task 1 Support of training: Special focus will be made on most relevant risk group 3 and 4 emerging and re-emerging pathogens identified in framework of WP4. It is envisaged that the programme will increase the overall competence of partners and member states. In consequence it will enhance general European capacity, to identify and work with highly pathogenic microorganisms using safe and standard practices. While this WP will enable training of a limited number of specific bacteriological or virological methods through nomination and consensus opinion, the main focus will be on broad training sessions encompassing diagnostic processes, laboratory methodology and biorisk management. Travel costs for participating in training courses will be borne by partners requesting training. The cost of hosting and developing a training session will be covered by the budget of the hosting partner. Training will also be available for Collaborating Partners on their own account. For each partner of the JA 2 training courses are budgeted. It will be expected that 10 partners will offer different topical training courses.

Task 2 Development of a training curriculum: The lead and co-lead partner will collate information on formal training programmes already available within the network and where required, develop bespoke training. These will then be matched with training needs. We envisage training sessions to involve theoretical instruction followed by group work-through on actual examples utilizing the training topic, followed by group discussion. Partners will compile mandatory training reports after each session; this information will include detailed description of how training has supported partner laboratories. Reports will also be made available for the evaluation work package. In this way all partners will play key roles in modifying the training sessions accordingly. Moreover, the leader and co-leader will aid main JA-coordinators in identifying and aiding the selected suitable partner that are able to provide specific training in case of an outbreak requiring a European response. If required, external experts will be consulted or invited to provide specific topics of training.

The training activities under inter-epidemic mode will be divided into four main categories:

a. Diagnostic algorithms. Primarily intended for clinical microbiologists, medical doctors and reference laboratory managers who are responsible for diagnostic processes, selection of methods analyses of results and reporting of diagnosis. This session will be run in the form of a workshop and based on a syndromic presentation compiled from a series of set examples derived from actual events. It will be developed to be as pathogen inclusive as possible and highlight the utility of such algorithms in infection control, biosafety/biosecurity and the importance of quality management. We expect that recent experience with imported VHFs will provide valuable knowledge for decision chains of differential diagnosis.

b. Laboratory methods. Primarily intended for laboratory staff involved in diagnostic processes at the partner institutes and organizations. These sessions will train in best practice for: preparation, running and analysis of results for identification and typing of highly pathogenic microorganisms. It will also include a focus on standards of assay validation for new and established methods, highlighting the importance of quality management. We envisage close cooperation with EQAs implemented in WP6 as it will build on the specific EQAEs reports to identify the
laboratory training needs
COORDINATOR

ROBERT KOCH-INSTITUT (RKI)
Nordufer 20
13353 Berlin
Germany
WEBSITE: http://www.rki.de

PARTNERS

ISTITUTO NAZIONALE PER LE MALATTIEINFETTIVE LAZZARO SPALLANZANI-ISTITUTO DI RICOVERO E CURA A CARATTERESCIENTIFICO
Street: Via Portuense 292
City: 00149 Rome
Country: Italy
Website: http://www.rki.de

ISTITUTO NAZIONALE PER LE MALATTIEINFETTIVE LAZZARO SPALLANZANI-ISTITUTO DI RICOVERO E CURA A CARATTERESCIENTIFICO
Street: Via Portuense 292
City: 00149 Rome
Country: Italy
Website: http://www.rki.de

ISTITUTO NAZIONALE PER LE MALATTIEINFETTIVE LAZZARO SPALLANZANI-ISTITUTO DI RICOVERO E CURA A CARATTERESCIENTIFICO
Street: Via Portuense 292
City: 00149 Rome
Country: Italy
Website: http://www.rki.de
OSTERREICHISCHE AGENTUR FUR GESUNDHEIT UND ERNAHRUNGSSICHERHEIT GMBH
Street: SPARGELFELDSTRASSE 191
City: 1220 WIEN 400
Country: Austria
Website: http://www.rki.de

CENTRUM VOOR ONDERZOEK IN DIERGENEESKUNDE EN AGROCHEMIE - CODA
Street: Groeselenberg 99
City: 1180 BRUXELLES
Country: Belgium
Website: http://www.rki.de

SCIENSANO
Street: JULIETTE WYTMANSTRAAT 14
City: BRUSSELS
Country: Belgium
Website: http://www.rki.de

NATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES
Street: blvd. Yanko Sakazov 26
City: 1504 SOFIA
Country: Bulgaria
Website: http://www.rki.de
NATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES
Street: blvd. Yanko Sakazov 26
City: 1504 SOFIA
Country: Bulgaria
Website: http://www.rki.de

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Country: Bulgaria
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Country: Bulgaria
Website: http://www.rki.de

NATIONAL CENTER OF INFECTIOUS AND PARASITIC DISEASES
Street: blvd. Yanko Sakazov 26
City: 1504 SOFIA
Country: Bulgaria
Website: http://www.rki.de

NATSIONALEN TSENTAR PO TRANSFUZIONNA HEMATOLOGIYA
Street: Str Bratia Miladinovi
City: 1202 Sofia
Country: Bulgaria
Website: http://www.rki.de
<table>
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<td>Estonia</td>
<td><a href="http://www.rki.de">http://www.rki.de</a></td>
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TERVISEAMET
Street: Paldiski mnt 81
City: 10617 Tallinn
Country: Estonia
Website: http://www.rki.de

TERVEYDEN JA HYVINVOINNIN LAITOS
Street: MANNERHEIMINTIE 166
City: 00271 HELSINKI 30
Country: Finland
Website: http://www.rki.de

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
Street: 101 Rue de Tolbiac
City: 75654 PARIS
CEDEX 13
Country: France
Website: http://www.rki.de
INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
Street: 101 Rue de Tolbiac
City: 75654 PARIS
CEDEX 13
Country: France
Website: http://www.rki.de

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
Street: 101 Rue de Tolbiac
City: 75654 PARIS
CEDEX 13
Country: France
Website: http://www.rki.de

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE
Street: 101 Rue de Tolbiac
City: 75654 PARIS
CEDEX 13
Country: France
Website: http://www.rki.de

MINISTERE DE LA DEFENSE
Street: Direction Generale de l'Armement DT/SDP 60 Boulevard du General Martial Valin CS2162375509
City: PARIS
CEDEX 15
Country: France
Website: http://www.rki.de

MINISTERE DE LA DEFENSE
Street: Direction Generale de l'Armement DT/SDP 60 Boulevard du General Martial Valin CS2162375509
City: PARIS
CEDEX 15
Country: France
MINISTERE DE LA DEFENSE
Street: Direction Generale de l'Armement DT/SDP 60 Boulevard du General Martial Valin CS2162375509
City: PARIS
CEDEX 15
Country: France
Website: http://www.rki.de

MINISTERE DE LA DEFENSE
Street: Direction Generale de l'Armement DT/SDP 60 Boulevard du General Martial Valin CS2162375509
City: PARIS
CEDEX 15
Country: France
Website: http://www.rki.de

MINISTERE DE LA DEFENSE
Street: Direction Generale de l'Armement DT/SDP 60 Boulevard du General Martial Valin CS2162375509
City: PARIS
CEDEX 15
Country: France
Website: http://www.rki.de

BUNDESMINISTERIUM DER VERTEIDIGUNG
Street: FONTAINENGRABEN 150
City: 53123 BONN
Country: Germany
Website: http://www.rki.de

BUNDESMINISTERIUM DER VERTEIDIGUNG
Street: FONTAINENGRABEN 150
City: 53123 BONN
Country: Germany
Website: http://www.rki.de
Street: SUDUFER 10
City: 17493 GREIFSWALD-INSEL RIEMS
Country: Germany
Website: http://www.rki.de

PHILIPPS UNIVERSITAET MARBURG
Street: Biegenstrasse 10
City: 35032 MARBURG
Country: Germany
Website: http://www.rki.de

BERNHARD-NOCHT-INSTITUT FUER TROPENMEDIZIN
Street: BERNHARD-NOCHT-STRASSE 74
City: 20359 HAMBURG
Country: Germany
Website: http://www.rki.de
ISTITUTO ZOO PROFILATTICO SPERIMENTALE DELLA LOMBARDIA E DELL'EMILIA ROMAGNA BRUNO UBERTINI
Street: VIA ANTONIO BIANCHI 9
City: 25124 BRESCIA
Country: Italy
Website: http://www.rki.de

NACIONALINE VISUOMENES SVEIKATOS PRIEZIUROS LABORATORIJA
Street: Zolyno str. 36
City: 10210 Vilnius
Country: Lithuania
Website: http://www.rki.de

RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU
Street: Antonie Van Leeuwenhoeklaan 9
City: 3721 MA BILTHOVEN
Country: Netherlands
Website: http://www.rki.de
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU
Street: Antonie Van Leeuwenhoeklaan 9
City: 3721 MA BILTHOVEN
1
Country: Netherlands
Website: http://www.rki.de

FOLKEHELSEINSTITUTTET
Street: Marcus Thranesgate 6
City: 0473 OSLO

Country: Norway
Website: http://www.rki.de
FOLKEHELSEINSTITUTTET
Street: Marcus Thranesgate 6
City: 0473 OSLO
Country: Norway
Website: http://www.rki.de

VETERINAERINSTITUTTET - NORWEGIAN VETERINARY INSTITUTE
Street: Ullevaalsveien 68
City: 0454 OSLO
Country: Norway
Website: http://www.rki.de

VETERINAERINSTITUTTET - NORWEGIAN VETERINARY INSTITUTE
Street: Ullevaalsveien 68
City: 0454 OSLO
Country: Norway
Website: http://www.rki.de

VETERINAERINSTITUTTET - NORWEGIAN VETERINARY INSTITUTE
Street: Ullevaalsveien 68
City: 0454 OSLO
Country: Norway
Website: http://www.rki.de

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Street: Ullevaalsveien 68
City: 0454 OSLO
Country: Norway
Website: http://www.rki.de
Country: Poland
Website: http://www.rki.de

INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE
Street: AVENIDA PADRE CRUZ
City: 1649-016 LISBOA

Country: Portugal
Website: http://www.rki.de
INSTITUTUL NATIONAL DE SANATATE PUBLICA
Street: STR DR LEONTE ANASTASIEVICI 1-3
City: 050463 BUCURESTI
Country: Romania
Website: http://www.rki.de

UNIVERZA V LJUBLJANI
Street: KONGRESNI TRG 12
City: 1000 LJUBLJANA
Country: Slovenia
Website: http://www.rki.de
UNIVERZA V LJUBLJANI
Street: KONGRESNI TRG 12
City: 1000 LJUBLJANA
Country: Slovenia
Website: http://www.rki.de

FUNDACION VASCA DE INNOVACION E INVESTIGACION SANITARIAS
Street: RONDA DE AZKUE,1
City: 48902 BARAKALDO
Country: Spain
Website: http://www.rki.de
<table>
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<tr>
<td>Spain</td>
<td>28029 MADRID</td>
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Department of Health
Street: Waterloo Rd
City: SE1 8UG London
Country: United Kingdom
Website: http://www.rki.de

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM
Street: 's Gravendijkwal 230
City: 3015 CE ROTTERDAM
Country: Netherlands
Website: http://www.rki.de

INSTITUTUL NATIONAL DE CERCETARE DEZVOLTARE PENTRU MICROBIOLOGIE SI IMUNOLOGIE
Street: SPLAIUL INDEPENDENȚEI
City: 050096 BUCUREȘTI
Country: Romania
Website: http://www.rki.de
INSTITUTUL NATIONAL DE CERCETARE DEZVOLTARE PENTRU MICROBIOLOGIE SI IMUNOLOGIE
Street: SPLAIUL INDEPENDENȚEI
City: 050096 BUCUREȘTI
Country: Romania
Website: http://www.rki.de

ORSZÁGOS KOZEGESZSEGÜGYI INTEZET
Street: Anna u. 5
City: 1221 BUDAPEST
Country: Hungary
Website: http://www.rki.de
Leaflet and newsletters
INSERM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 22/11/2017
Development of a leaflet for active dissemination of information on the JA. A bi-annual newsletter will be developed.

Layman version of the final report
INSERM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 18/09/2019
Development of a layman version of the final report for public dissemination.

Final report
RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 18/09/2019
Documentation of all activities. A public version will be developed.

Report on laboratory support for physicians treating patients with high threat infections
EMC
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 12/09/2019
IEM: Report on laboratory support including chemical chemistry considered essential by physicians treating patients with high threat pathogen infections (M45)

Publication on veterinary and medical
laboratory support in outbreaks of zoonoses
EMC
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 01/08/2019
IEM: Publication on commonalities and differences in laboratory support of a zoonotic disease outbreak in veterinary and medical laboratories will be developed and published.

Reports on working groups outcomes and diagnostics
INMI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 12/07/2019
IEM: Interim report and final reports on WP 5 including working groups activities assessing new and high-tech diagnostic methods for their applicability in outbreak response situations (M12, 28, 36, 46) could also include prototypes of diagnostics.

List reagents and diagnostics
INMI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 12/07/2019
IEM: The relevant target pathogens will be identified together with WP4. A list of reagents and diagnostics as well as of reference samples will be provided and shared among partners or with other relevant networks that will be proposed for implementation and application. Could also include prototypes of diagnostics and reagents delivered to partners for application in ORM.

Document on diagnostic activities in ORM
INMI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 12/07/2019
ORM: Document resulting from activities performed in outbreak response mode (M6, M12, M18, M24, M30, M36, M45.)
EQAE
RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 12/07/2019
IEM: Provisions of EQAE on bacteria (1. RKI) and viruses (16. UMR) as well as unknown agents (RKI/UMR) (M12, M24, M35). Public version of the report will be developed.

Repository sustainability plan
RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 12/07/2019
IEM: Repository sustainability plan – collaboration agreement with third parties

Implementation of biorisk check list
RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 12/07/2019
IEM: Reports on the implementation of the biorisk management check list (M12, M24, M36, M46)

Ad-hoc proficiency tests
RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERVE)
Published on: 12/07/2019
ORM: Provision of ad-hoc proficiency tests and reference material in ORM (1. RKI/ 16. UMR)

ORM Reports
INMI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
In case of an outbreak of infectious agents that requires a European response,
dissemination in ORM

INSERM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
Reports on activities in ORM (M6, M12, M18, M24, M30, M36, M44 or ad-hoc); a public version of the report will be developed.

evaluation of activities in ORM

PHE
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
Evaluation of activities in outbreak response mode (M6, 12, 18, 24, 30, 36, 44)

inventory of networks relevant for interoperability assessment

EMC
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
IEM: Protocol for network interaction during outbreaks will be developed for further discussion and agreement with other networks and stakeholders. A special MoU/Collaborative Agreement and an Action Plan to define the collaboration between ECDC and the JA will be prepared. A public version of the protocol will be developed.

recommendations in ORM

EMC
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
Provision of ad hoc advise, in response to questions addressed by commission or other stakeholders in ORM (M6, 12, 18, 24, 30, 36, 46)
Reports on activities in ORM
RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
ORM: Reports on the activities in ORM (M6, M12, M18, M24, M30, M36, M44) (1. RKI/16. UMR)

Reports and training evaluation
FoHM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
IEM: Reports and training evaluation (M12, M24, M36, M46) (33. FoHM/ 4. PHE). Public version will be developed.

Report on wet-laboratory exercise
PHE
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
IEM: Report/evaluation of exercise. (34. PHE/33.FoMH). Public version will be developed.

Reports on training in ORM
FoHM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/06/2019
ORM: Report on evaluation and adaptation of training program including identification of suitable trainer(s). Development and offering of specific training program (methodology, biorisk management) (M6, M12, M18, M24, M30, M36, M46). Also practical outcome as provision of training.

Publication survey on Ebola laboratory response
EMC
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/11/2018
IEM: A publication survey on Ebola laboratory response will be provided as a basis for lessons learned and further improvement of networking.

Interim reports
RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 11/12/2017
Report on activities at 12 and 24 months. Public version will be developed.

Reports on dissemination
INSERM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 11/12/2017
Annual report on the dissemination activity (M12, M24, M36)

Training programmes
FoHM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 11/12/2017
IEM: Training programme (M9), revised program (M21); parts will be also public (33. FoHM/34. PHE)

MoU/Collaborative Agreement with ECDC
EMC
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 11/12/2017
A MoU/Collaborative Agreement between EMERGE and ECDC will be developed to ensure the close collaboration.

Consortium Agreement
RKI
Development and signature by all beneficiaries of the Consortium Agreement.

Evaluation reports and interim reports

PHE
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 08/09/2017
Reports on evaluation of each WP (M3, 6, 9, 12, 15, 18, 24) or Meeting 1-4. Interim reports (M12, M24).

Plan for transition from IEM to ORM

INMI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 18/11/2016
Generic plan and detailed plan according to the situation. Public version will be developed.

Steering Committee and Advisory board

PHE
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 18/11/2016
Set up of the Steering Committee and Advisory board for evaluation of the correct implementation and performing of the JA and for drawing of recommendations.

Dissemination tool kit

INSERM
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 16/08/2016
Release of the project dissemination toolkit describing the dissemination mechanisms and target audience.
Website

RKI
Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE)
Published on: 26/02/2016
Establishment of the website for the JA.