

BUNDESMINISTERIUM FUER GESUNDHEIT	23
BUNDESMINISTERIUM FUER GESUNDHEIT	23
BUNDESMINISTERIUM FUER GESUNDHEIT	23
BUNDESMINISTERIUM FUER GESUNDHEIT	23
MINISTRY OF CIVIL AFFAIRS	23
MINISTRY OF CIVIL AFFAIRS	23
MINISTRY OF CIVIL AFFAIRS	23
MINISTRY OF CIVIL AFFAIRS	23
HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	23
HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	23
HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	23
HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	23
HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	23
HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	23
STATNI USTAV JADERNE, CHEMICKE A BIOLOGICKE OCHRANY vvi	23
STATENS SERUM INSTITUT	23
STATENS SERUM INSTITUT	23
STATENS SERUM INSTITUT	23
STATENS SERUM INSTITUT	23
SOTSIAALMINISTEERIUM	23
SOTSIAALMINISTEERIUM	23
SOTSIAALMINISTEERIUM	23
SOTSIAALMINISTEERIUM	23
SOTSIAALMINISTEERIUM	23
MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE	23
MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE	23
MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE	23
MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE	23
MINISTERE DES AFFAIRES SOCIALES ET DE LA SANTE	23
KENTRO ELENCHOU & PROLIPSIS NOSIMATON	23
ETHNIKOS ORGANISMOS DIMOSIAS YGEIAS	23
ETHNIKOS ORGANISMOS DIMOSIAS YGEIAS	23
THE NATIONAL PUBLIC HEALTH ORGANIZATION(NPHO)	23
ORSZAGOS KOZEGESZSEGUGYI INTEZET	23
ORSZAGOS KOZEGESZSEGUGYI INTEZET	23
State Emergency Medical service	23
State Emergency Medical service	23
LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA	23
LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA	23
LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA	23
Ministry for Health - Government of Malta	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23

RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	23
HELSE DIREKTORATE	23
HELSE DIREKTORATE	23
HELSE DIREKTORATE	23
HELSE DIREKTORATE	23
NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO-PANSTWOWY ZAKLAD HIGIENY	23
NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO-PANSTWOWY ZAKLAD HIGIENY	23
NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO-PANSTWOWY ZAKLAD HIGIENY	23
NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO-PANSTWOWY ZAKLAD HIGIENY	23
MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA	23
MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA	23
MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA	23
INSTITUT ZA JAVNO ZDRAVLJE SRBIJE 'MILAN JOVANOVIC - BATUT'	23
NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	23
NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	23
NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	23
NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	23
NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
INSTITUTO DE SALUD CARLOS III	23
FOLKHALSOMYNDIGHETEN	23
FOLKHALSOMYNDIGHETEN	23
FOLKHALSOMYNDIGHETEN	23
FOLKHALSOMYNDIGHETEN	23
FOLKHALSOMYNDIGHETEN	23
FOLKHALSOMYNDIGHETEN	23
FOLKHALSOMYNDIGHETEN	23
FOLKHALSOMYNDIGHETEN	23
Department of Health	23
Department of Health	23
Department of Health	23
Department of Health	23
Department of Health	23
Department of Health	23
Department of Health	23
Department of Health	23

HEALTH SERVICE EXECUTIVE HSE	23
HEALTH SERVICE EXECUTIVE HSE	23
HEALTH SERVICE EXECUTIVE HSE	23
HEALTH SERVICE EXECUTIVE HSE	23
HEALTH SERVICE EXECUTIVE HSE	23
HEALTH SERVICE EXECUTIVE HSE	23
AGENTIA NATIONALA PENTRU SANATATE PUBLICA	23
AGENTIA NATIONALA PENTRU SANATATE PUBLICA	23
AGENTIA NATIONALA PENTRU SANATATE PUBLICA	23
Outputs	46
Layman report	46
Final report	46
A blueprint of dissemination	46
Communication and dissemination report	46
Midterm internal evaluation reports	46
Final internal evaluation report	46
Final external evaluation report	46
Sustainability Report	46
Reports on improving IHR implementation	46
Report on international collaboration between authorities during crises	46
Report on the use exercises and AAR	46
Report on lessons learned from Covid-19	46
Report on assurance of high quality of diagnostic	46
Report on modern molecular diagnostic methods	46
Recommendations for risk management	46
Final training report	46
WP9 Final report	46
Report on existing facilities	46
Feasibility study report	46
Report on syndrome-based approach	46
Basic and advanced training curricula	46
Report on SOPs developed	46
Midterm external evaluation report	46
Chemical laboratory response network - scoping report	46
Review of planning and evaluation tools	46
Report on training needs	46
Fact-finding report	46
Interim report	46
Leaflet	46
Website	46
Evaluation plan	46
Guidance on sustainability	46
WP5 Work plan	46

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action

JA2015 - GPSD [705038]

START DATE: 01/04/2019

END DATE: 31/03/2023

DURATION: 36 month(s)

CURRENT STATUS: Ongoing

PROGRAMME TITLE: 3rd Health Programme (2014-2020)

PROGRAMME PRIORITY: -

CALL: Joint Actions 2018

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

EC CONTRIBUTION: 7900000 EUR

KEYWORDS: Core Capacity, Health Security, Ihr, Preparedness, Public Health, Response

Project abstract

The SHARP Joint Action will strengthen implementation of Decision 1082/2013/EU, supporting the EU level preparedness and responses to health threats and the implementation of the International Health Regulations (2005). The Joint Action implements actions mentioned in Annex 1 of the Annual Work plan 2018 of the EU Health Programme 2014-2020.

Through the Joint Action, the member and partner states and the Unions common ability to prevent, detect and respond to biological outbreaks, chemical contamination and environmental and unknown threats to human health will be strengthened. Special efforts will be employed to fill gaps that have been or will be identified in priority countries (countries that have biggest gaps in the capacity required for full IHR capability). The Joint action consists of 10 Work Packages, covering core public health capacities according to the IHR (2005). In addition to a coordination function, these will cover areas such as Communication, Evaluation, Sustainability, IHR core capacity, Preparedness, Laboratories, Training and exercises, Chemical threats and Clinical management.

SHARP will also collaborate with several other Joint Actions, specifically the "Healthy Gateways" that addresses Points of Entry, the Joint Action on Vaccination (EU-JAV) and the Joint Action on Antimicrobial Resistance (EU-JAMRAI).

The partnership of the joint action consists of 26 Associated Partners and 33 Affiliated Entities, which all will receive Commission co-funding. In addition there are 9 Collaborating Partners that will self-fund all activities that they participate in. Totally 30 countries (24 EU members, 3 EEA/EFTA members and 3 European neighborhood countries) participate in the Joint Action. The SHARP JA will liaise with and collaborate with the ECDC, the WHO EURO regional office and the WHO Health Emergency and IHR unit in Lyon, and IANPHI in relevant activities. Special emphasis will be made to avoid duplication of work for the member states.

Work package

Work Package 1: Coordination

Start month: 1

End month: 36

Work Package Leader: THL

Coordinator: THL

Co-Coordinators: INMI, RKI

Participating partners: all JA partners and affiliated entities

The JA includes 10 work packages:

- Horizontal: WP1 Coordination, WP2 Dissemination, WP3 Evaluation, WP4 Sustainability and policy development, WP8 Training and local exercises, exchange of working practices;
- Core work packages: WP5 IHR core capacity strengthening and assessment, WP6 Preparedness and response planning; WP7 Laboratory preparedness, WP9 Chemical safety and chemical threats and WP10 Case management and Infection Prevention and Control Preparedness.

The Coordinator ensures that the project work packages work together in order to gain the objectives of the Joint Action. The coordinator leads the project with the support of the steering committee, oversees the execution of the Work Packages and may take part in their execution, as appropriate. The coordinator will facilitate the building of country ownership together with the Work Package leaders.

Tasks of the Coordinator according to the Guide for applicants:

- Monitor that the action is implemented properly;
- Act as the intermediary for all communications between the beneficiaries and the Agency, unless the MGA specifies otherwise;
- Request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;
- Submit the deliverables and reports to the Agency;
- Ensure that all payments are made to the other beneficiaries without unjustified delay;
- Inform the Agency of the amounts paid to each beneficiary, when required in the MGA or requested by the Agency, or in the context of ex post Audits.

The management structure of the JA consists of THL Coordination Team, Steering Committee and Advisory Board. In addition, each WP has its own leadership and internal meetings/teleconferences.

The Co-coordinators are responsible for supporting in quality assurance of deliverables and representing the joint action in international meetings and conferences when Coordinator is unable to do it. More detailed ToR will be agreed with the Coordinator.

Steering Committee (SC) is chaired by THL. Each WP has one vote in the SC, but both WP lead and co-lead can participate. Observers are invited from Chafea, DG SANTE, ECDC and from other organisations as needed. The tasks of the SC include support to the Coordinator in (i) supervising the overall project management and internal project communication, (ii) monitoring the use of budget and agreeing on possible changes in the allocations, (iii) monitoring the progress of the JA against the activities and timetable planned and agreeing on possible changes, (iv) reporting to EC through THL.

The SC will meet at least 7 times during the implementation of the JA. The meetings will be organized in connection of Kick-off meeting, Partnership Forums and other major meetings.

In addition to meeting face-to-face, the SC will discuss current issues via phone/skype meetings at least every second month.

In case of European cross-border outbreak, the SC can provide technical advice, if asked.

Advisory Board (AB) will be set up by the SC, and members will be invited from EC (Chafea, DG SANTE, DG ECHO), the ECDC, WHO Europe, and other actors like e.g., IANPHI – the International Association of National Public Health Institutes, Public Health Agency, Canada, SCHEER Rapid Risk Assessment Working Group for Chemical Threats and JA Healthy Gateways, as well as other experts to be identified in the beginning of the action. The Steering Committee of SHARP will decide whom to invite into the AB at its first meeting. The Board will choose a chairperson; and it will advise the JA Steering Committee in substantial issues concerning the core work packages. The Advisory Board will be invited to have their meeting in connection with Kick-off meeting and Partnership Forums, and the members will be invited to the Closing conference. The Board is pl

Work Package 2: Communication and dissemination

Start month: 1

End month: 36

Work Package Leader: DH

Lead: Public Health Wales – affiliated to DH/PHE

Co-lead: THL

A specific and appropriate communications and dissemination strategy ensuring visibility for, and awareness of, the project will be developed, implemented and evaluated. The outcome of this will mean greater awareness of the Joint Action and its benefits to the European population.

The communications WP aims to generate long term, sustainable benefits by increasing communications and dissemination capability and capacity across the work packages.

The intention is to leave a blueprint for effective programme communications for future Joint Actions in collaboration with WP4.

The Work package will address:

1. Dissemination about the project, its events, reports and results
2. Communication of key messages to relevant audiences, about the substance of the JA, including recommendations

This WP will comprise six phases of work described below:

Task 2.1: Set Communications Objectives (M1-3)

- Understand the business and public health objectives of the programme
- Set out specific communications objectives arising from these, including both internal programme communications, and external communications
- Agree dissemination plan with the Joint Action Steering committee
- Develop and agree sign-off process for latter stages of communications strategy development
- Hold Communications Planning session with Programme Coordination Team to work through objectives and key elements below to ensure these reflect and respond to the objectives set out by the other Work Packages.

Task 2.2: Audience Needs (M4-6)

- Identify and segment internal and external audiences for the programme
- Conduct stakeholder analysis, segmenting audience into levels of interest and influence in readiness for development of channel strategy and key messages
- Hold communications workshops with Work package communications leads to understand their specific needs and challenges (e.g. system maturity, technology);
- Identify language needs – including which countries have statutory duties to communicate in particular languages;
- Consider any specific cultural issues that will help or hinder effective communications, including language, access to resources and channels in communications. The main communication language of the JA will be English, limited amount of translations can be offered.

Task 2.3: Key Messages (M7-10)

- Produce and agree a set of key messages for each stage of the programme which reflect the work of the Work Packages.
- Tailor messages where appropriate
- Translate messages where appropriate
- Adapt messages to suitable channels

Task 2.4: Channels (M7-10)

- Identify a channel mix, giving consideration to language requirements or whether a single overarching multilingual channel is more appropriate
- Develop a channel strategy which will include actions on visibility and awareness, including use of social media. Consider using conferences, journals, press releases alongside existing local communications networks specific to IHR where these exist.
- Commission a bespoke website for the programme
- Set up social media channels like e.g. Twitter, LinkedIn, Facebook etc.
- Identify long-term, sustainable ownership for channels
- Commission programme branding to run through all channels and other project documentation

Task 2.5: Communications planning (M9-12) and implementation (M11- 35)

- Develop a communications plan incorporating the above elements, including tailored communications toolkits for use by Work package leads
- Work with WP1 to disseminate project aims, progress and results, especially in connection with the Kick-off meeting, two Partnership Forums, the thematic meeting during Finnish EU presidency in autumn 2019 and Final meeting of SHARP.
- Work with WP8 to ensure coordinated dissemination of toolkits above alongside exchange of working practices.
- Implement communications plan

Task 2.6: Measurement and evalu

Work Package 3: Evaluation of the action

Start month: 1

End month: 36

Work Package Leader: HCDPCP(KEELPNO)

The expected results of this Work Package are:

- An evaluation plan/strategy and interface developed to be used by all project partners
- Methods and tools for internal project progress monitoring, quality assurance indexing and internal evaluation procedures developed
- The project's progress and timekeeping monitored
- Intermediate and final project results and outcomes evaluated
- Possible deficiencies in work packages' tasks identified, as well as mitigation strategies proposed, so that deliverables meet set quality standards.

The evaluation will draw on routine reports produced by the partners during implementation and will include additional investigations by external experts.

The WP tasks are broken down as follows:

Task 3.1 Evaluation plan development

The evaluation plan will examine the process, outputs and outcome(s) (internal, external) of the WPs of the project through systematic review in terms of results (if objectives were met) as well as in terms of quality standards met. The common evaluation plan will be designed based on the information regarding the finalized tasks of each WP and planned milestones, available at M1 from each WP leader.

Furthermore, the evaluation plan will present the methodology which will be used for the internal and external evaluation of the Project. It will specify the evaluation strategy and objectives, indicators (based on Specific objective tables in chapter 2.2.), as well as the expected outcomes, deliverables and milestones. It will also define:

- the standards that will be used,
- the internal monitoring system
- the timetable for the key stakeholders involved.

Finally, it will present the external evaluation procedures including evaluation criteria, questions, indicators (2.2) and data collection and analysis methods.

Task 3.2 On-going internal evaluation

Internal evaluation procedures will be applied throughout the duration of the project and will emphasize on the efficacy of WP tasks, focusing on:

- Measuring to what extent the project's general and specific objectives have been achieved.
- Assessing the processes related to the project, to ensure that the project activities are implemented as expected.
- Measuring to what extent the project has reached / achieved its main outputs (deliverables, milestones, main results).
- Measuring to what extent the outcomes of the project, meet the needs of the project's target groups identified by WP leads
- Measuring to what extent the project has engaged other sectors on national level (e.g. food safety, environmental health, civil protection)

At mid stage of the project cycle, a process evaluation (formative) will take place, focusing on the planning and organization of the project activities. In particular, on whether

- activities were implemented according to the initial plan,
- obstacles and difficulties were swiftly detected and mitigated

Standard evaluation tools (i.e. surveys and interviews) will be used to extract preliminary results, regarding the timeliness and implementation quality of WP tasks. The role of the mid-stage evaluation is to provide feedback as far as potential changes required in order to improve processes and activities of the project, increasing their potential impact on its set target groups.

The evaluation tools (a log-frame matrix for each WP, a master scoring model, a set of summative and formative tools both quantitative and qualitative as Dartboard, structured and/or semi-structured interviews, focus groups etc.) used for evaluating the JA deliverables will be based on a set of indicators on the implementation of planned activities. Outcome/output measurements will serve as a continuous assessment tool for each WP. All deliverables and information from meetings and training events and workshops (agenda, participants' lists and minutes) will be collected and analyzed for evaluation purposes. Organizers and participants of all events and meetin

Work Package 4: Integration in National Policies and Sustainability

Start month: 1

End month: 36

Work Package Leader: MOH-FR

Key activities carried out by the different WPs of this Joint Action are expected to improve preparedness and response planning, and the purpose of this WP is to build a sustainability plan, to ensure uptake and sustainability of the Joint Action outcomes from WP5 to WP10 at EU, national and/or regional level, and enabling to comply with the implementation of the IHR (2005) and relating Decision 1082/2013/EU.

Task 4.1. Guidance tool (M7-13)

Task leader: MOH-FR

Participants: THL (FI), PHW (UK), HCDCP (GR), RIVM (NL), FOHM (SE), HD (NO), ISCIII (ES), RKI (DE), INMI (IT), IPHS (RS), PHE/DH (UK), NIJZ (SI)

The purpose of task 4.1 is to develop a guidance tool aiming at ensuring that all core WPs take into account the sustainability of their outcomes within their work and reports. WP4 task leaders will closely follow-up and contribute to the work done by other WPs through participation at meetings, iterative process of deliverables, observation and guidance on other WP's outputs. A workshop will be organized with the Steering Committee members to draft the guidance frame.

Task 4.2. Selection of best practices (M12-18)

Task leader: RIVM-NL

Participants: THL (FI), PHW (UK), HCDCP (GR), RIVM (NL), FOHM (SE), HD (NO), ISCIII (ES), RKI (DE), INMI (IT), IPHS (RS), PHE/DH (UK), NIJZ (SI), SUJCHBO (CZ).

The purpose of task 4.2 is to select best practices for integration into sustainability plan. Pilot actions supporting a sustainable integration of best practices will be developed based on the interim internal evaluation report (M12) in collaboration with WP3, and based on the review of the existing IHR and laboratory preparedness and response tools and mechanisms done by WP6. Identified actions will be included into the sustainability plan. This selection will be developed in close collaboration with the Health Security Committee, during its bi-annual meeting. A workshop 2 (M18) will be organized with the Steering Committee, the Advisory Board and the Health Security Committee to review those selected outcomes and confer about the next steps, to be included in the sustainability plan and national policies. The integration of some selected best practices into national policies will be piloted throughout the project in collaboration with other WPs.

Task 4.3. Development of the SHARP sustainability plan (M19-24)

Task leader: MOH-FR

Participants: THL (FI), PHW (UK), HCDCP (GR), RIVM (NL), FOHM (SE), HD (NO), ISCIII (ES), RKI (DE), INMI (IT), IPHS (RS), PHE/DH (UK), NIJZ (SI), MCA(B/H), MFH (Malta).

The purpose of this task is to develop a generic sustainability plan to foster long term integration of selected WP outcomes into EU/ national / regional policies and mechanisms and to define the conditions for operationalization. It will include a selection of priorities and best practices, the identification of required resources (budget, training, HR) and partners to be involved, an advocacy strategy on identified priorities in coordination with WP2 and WP3, and a sustainable

communication and coordination between Member States. This sustainability plan will be developed in close collaboration with WP1 and WP5 and the Health Security Committee members, to ensure optimal uptake. It is expected to contribute to the objectives and indicators related to national legislations, policy and financing, as outlined in particular in WHO Joint External Evaluation tool. A workshop 3 involving SHARP Steering Committee and Advisory Board as well as the EC Health Security Committee members will be organized to present a final draft of the sustainability report at M24.

Work Package 5: IHR core capacity strengthening and assessment

Start month: 1

End month: 36

Work Package Leader: FOHM

Expected results

1. Participating lower GNI countries who have not conducted a Joint External Evaluation (JEE) supported to get prepared for an external assessment of their IHR Core Capacity, i.e. JEE or other agreed standardised external evaluation process; countries helped in the assessment of capacity for future development and sustainability of necessary core capacity as required by IHR and Decision 1082/2013/EU;
2. Participating lower GNI that have conducted a JEE; assisted by addressing problem areas identified in the post JEE country reports.
3. Challenges in national and international collaboration between governments and national authorities identified, and measures elaborated for the operationalization of obligations related to response from health systems, cross-sectoral efforts and effective assistance between Member States when needed
4. The usefulness of using information from national and international exercises and after action reviews in assessing the state of public health preparedness in the EU evaluated

Within the work package, up to twelve selected lower GNI countries will be funded for participation in the planned workshops and teleconferences/webinars and for preparatory work in between. The activities will be divided into four main parts; the first part focusing on increasing knowledge about the evaluation process and best practice in preparation it, the second part focusing on post-evaluation follow up of joint identified weaknesses in core capacities, the third part focusing on cross country collaboration in emergencies, the fourth part on assessing the usefulness of including exercises and after action reviews in evaluations of preparedness.

Task 5.1 – Improving IHR implementation

Lead: SE (FoHM); Co-lead: SI (NIJZ), LT(SEMS), PL (NIZP-PZH)

Participants: GR (HCDCP), ES (ISCIII), HR (CIPH), LT (MOHLT), MT (MFH), RS (IPHS), BA (MCA), MD (NAPH), FI (THL), IT (MOH), FR (MOH), UK (DH/PHE), NL (RIVM), NO(FHI)

Workshops and teleconferences/webinars - Workshops under subtasks 5.1.1 and 5.1.2 will be hosted together to further enable exchange of knowledge between countries. Workshops 1 and 2 will be joint and hosted by SEMS (SI), workshops 3 and 4 will be joint and hosted by NIJZ (LV) and workshops 5 and 6 will be joint and hosted by NIZP-PZH (PL). Partners from low GNI-countries included in this WP will participate in all workshops. Partners from participating high GNI countries (NL, IT, UK, FI, DE, except SE and NO that leads WP) will participate to share knowledge and best practice (when applicable).

Subtask 5.1.1 – Increasing knowledge about the practicalities and added value of external evaluation processes Activities supporting expected result 1

Workshops 1, 3 and 6

Participation

IHR national focal points and/or participants from national public health agencies (or analogous as applicable) responsible for IHR implementation from lower GNI countries as well as representatives from WHO and ECDC and other partner countries who have already performed a JEE and can contribute with knowledge of the process, benefits and challenges with it.

Outcome

Selected low GNI countries will have been assisted in preparing for a JEE by information and best practice sharing from other participating countries thereby gaining better knowledge about the JEE process and how to prepare for one should they decide to do one. This process by itself will increase the participating countries knowledge on IHR preparedness and thereby their general preparedness. The knowledge gained will be tested by pre- and post- work out questionnaires.

Subtask 5.1.2 Facilitating strengthening of selected core capacities. Workshops 2,4 and 6

For selected countries that who have already performed a JEE

Three common areas in need of further development as identified by evaluation of the JEE country reports and the post JEE country action plans (if existing) will be addressed in yearly workshops and yearly follow up teleconferences/ webinars. F

Work Package 6: Preparedness and Response planning

Start month: 1

End month: 36

Work Package Leader: RIVM

Lead: RIVM (NL)/EMC (NL); Co-lead: ISCIII (ES)

Expected Results:

1. Development of an integrated multisectoral preparedness and response plan
2. Scenario for "Disease X" developed, simulated and evaluated
3. All hazard e-learnings and tabletop exercise protocols, using different methods for multisectoral collaboration developed, tested and evaluated
4. Best practices guidelines, both general and tailor-made standards for all hazard integrated preparedness and response planning are provided to all participating

countries. These are based on analysis of performances from “Disease X” scenario simulation and all hazards e-learnings and tabletop exercises, performed in WP6.

The specific objective of the WP6 will be achieved through the following tasks:

Task 6.1: Identifying core elements of an integrated multi-sectoral preparedness and response plan

Lead: RIVM; Participants: FI (THL and FFA), DE (RKI), IT (INMI and MoH), AU (AGES), UK (DH/PHE), ES (ISCIII) BA (MCA), HR (CIPH and UHID), CZ (SUJCHBO), HU (NNK), LV (SEMS), LT (MOHLT), MT (MFH), PL (NIZP-PZH and NVRI), PT (MS), RS (IPHS), SI (NIJZ).

Identification of core elements in the available IHR assessment tools in the Member States and JA partner countries for the different sectors (e.g. public health, clinical, biological and chemical). The specific needs and minimum requirements for the sectors involved in the IHR Preparedness and Response cycle (as defined in the ECDC Health Emergency Preparedness Self-Assessment (HEPSA) Tool) will be identified.

6.1.1: Review of international and/or national tools and planning instruments for preparedness and response focused on multisectoral integration for the public health laboratory services, clinical and chemical sectors

Lead: RIVM/EMC; input from WP5, WP7, WP9, WP10

6.1.1.2 Literature review

This integrative review of literature, websites, search for grey literature and collection of not-published tools used in practice by the participating countries will enlighten how different sectors and countries define “core elements”. This will be carried out to reach common understanding of terms, to find out which core elements are available and/or applied in preparedness and response planning for different sectors (i.e. public health, clinical, chemical, and others) and to identify gaps and overlaps. The outcome of the literature review will serve as basis for the subsequent workshop 6.1.1.3.

6.1.1.3 Workshop

Lead: MS, Portugal

Multisectoral collaboration: A workshop will be organized with the aim to collect relevant tools, instruments or core elements that were not identified in the literature review, or have different meaning or weight for different sectors or countries. The starting point for this workshop will be the outcome of the Literature review 6.1.1.2 as well as identified existing documents, such as ECDC Health Emergency Preparedness Self-Assessment (HEPSA) Tool, the Joint External Evaluation (JEE) reports, the, EU Laboratory Capability Monitoring System (EULabCap, 2016), WHO Laboratory assessment tool (2012), and the WHO Strategic framework for emergency preparedness (2017) (https://ecdc.europa.eu/sites/portal/files/documents/2016_EULabCap_EUreport_web_300418_final.pdf; https://www.who.int/ihr/publications/laboratory_tool/en/; <https://www.who.int/ihr/publications/9789241511827/en/>) and other documents as suggested by the experts from WP7, WP9 and WP10, and documents to be identified.

Outcome should be mutual understanding and agreement of terms, tools, instruments and core elements in the integrated multi-sectoral preparedness and response plans. Including other relevant sectors, for example the veterinary sector more tightly into the multi-sectoral plan will be discussed.

6.1.2: Achieving consensus among countries on the core elements of a multisectoral preparedness and response plan

Lead: RIVM/EMC, input from WP4 – W10

A checklist of preparedness and response aspects will be developed for sectors inte

Work Package 7: Laboratory preparedness and responsiveness

Start month: 1

End month: 36

Work Package Leader: RKI

The work package will be structured in specific tasks with task leaders, task co-leaders, and working groups for specific sub-tasks. Special funding will be given to task leaders and co-leaders as well as designated working group leaders to carry out specific activities together with other partners, while basic funding will be given to all partners to cover essential activities like participation in meetings, shipment of samples for EQAE and the repository.

Special attention will be given for partners from low GNI MS for their implementation in the various tasks of the WP.

Task 7.1 External Quality Assurance Exercise (EQAE) Lead: RKI/ZBS2, DE; Co-lead: UMR, DE (affiliated entity)

- RKI/ZBS2 and UMR will prepare, organize, and provide annual EQAEs on relevant bacteria (according to accreditation DIN EN ISO 17043) (topic 1.1) and viruses (topic 1.2) considering the actual risk assessment for highly infectious agents.
- Scenarios could include natural, accidental, or intentional outbreaks of infectious diseases. The EQAE will be embedded in interoperability exercises including PH/IHR whenever possible. Only for BSL4 laboratories, neutralization tests, using human or animal sera (according to availability), will be performed.
- Nominated partners and affiliated entities (laboratories) will participate in the EQAEs. For practical reasons, the number of participants in each EQAE will be limited to a maximum per JA partner country to be negotiated.
- The participants will be asked in advance for their capabilities to detect and characterize bacteria, viruses, and to conduct antibody detection as well as antimicrobial susceptibility testing for bacteria. Accordingly, they will receive adequately composed sample sets.
- In the framework of WP7, a proposal will be developed to stabilize the function of EQAE organization for diagnostics of highly pathogenic agents in Europe as well as

to ensure the long-term maintenance of the centralized bacterial repository.

Two topics:

1.1 EQAE on RG3 bacteria

1.2 EQAE on RG4 viruses

Common EQAE and simulation exercise will be planned. Ad-hoc EQAEs directed to specific pathogens and methods will be conducted in outbreak situations.

Task 7.2 Diagnostic approaches

Lead: INMI, IT; Co-lead: BwIM, DE (affiliated entity)

Laboratories represent one of the core capacities that must be consolidated and further developed for the implementation of IHR and strengthening core laboratory capacities is the main aim of this task. The task will consider the following aspects:

- Identification of relevant target pathogens including relevant RG2/3 agents for differential diagnoses; linkage with WP6.
- The evaluation of best diagnostic approaches and methods, including in-house and commercial diagnostic assays, will be done to define laboratory recommendations, including biosafety and shipment aspects, and evaluation/update of lab capabilities in the EU.
- For highly pathogenic infectious agents, very often in-house assays are used, but for some of these pathogens also commercial assays are available. In this case, the access to these assays especially might be easier than to develop own in-house tests, especially for lower GNI countries, and can provide better standardization of diagnostic procedures. On the other hand, the quality of evaluation of commercial assays is often not well demonstrated and this gap could be filled by activities in the network. Thus, we would like to consider both in-house and commercial assays for evaluation of their applicability in diagnostic laboratories. The results obtained during the previous JA EMERGE are used as a basis for the evaluation.
- Focusing on highly pathogenic infectious agents, this evaluation will generate networking added value to the existing EULabCap data base which is currently lacking this information. A mutual usage and exchange of these data bases is envisaged. The new Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices (IVDMD) will as well be

Work Package 8: Training and local exercises, exchange of working practices

Start month: 1

End month: 36

Work Package Leader: IPHS

Expected results:

- The level of IHR capacities to prevent, prepare, detect and respond to cross-border threats to health improved
- Practices related to IHR capacity building exchanged with the special emphasis to

strengthening the capacities of countries with GNI less than 90% of EU average ;

Cross-sectoral capacities for detection, preparedness and response to emerging public health threats scaled up.

This work package (WP8) will ensure synergies with other EU and global level activities related to strengthening the IHR implementation involved in training and exchange of work practices, for example HSC Action plan on preparedness and IHR implementation, WHO Action Plan to Improve Public Health Preparedness and Response in the WHO European Region, Health Programme actions and activities, such as the ongoing Healthy Gateways, JAV, JA AMR Commission frameworks; and on a global level with WHO and global health security frameworks and initiatives.

In general, WP8 will focus on applied activities rather than basic scientific research. A kick-off meeting between all countries involved in WP will initiate the activities of the project (3rd month). Another meeting will be held after finalisation of cross-sectoral training needs assessment (month 18th) to agree on the agenda and methodology of the advanced trainings.

All countries with GNI less than 90% of EU average are expected to participate at training activities.

Task 8.1. Assessment of the cross-sectoral training needs in JA partner countries related to preparedness and IHR implementation

Lead: IPHS, co-lead: ISCIII. Participation: DH (PHE), all institutions involved in the WP8

Subtask 8.1.1 An assessment of the cross-sectoral training needs of countries will be conducted (months 13th to 15th), building on the previously conducted ECDC and WHO training needs assessments, followed by analysis of results. No extra survey of training needs might be necessary. The analysis of reports from WHO Joint External Evaluations, Progress report on preparedness and response planning under decision 1082/2013/EU (art. 4) and EC/ECDC technical assessments will indicate areas where training may be required. Assessment results should be discussed with countries for their feedback and a report on assessment of the cross-sectoral training needs across countries (including region-specific needs). Lead: IPHS. Participation: PHE, FHI, NIZ-PZH, all institutions involved in the WP8.

Subtask 8.1.2 An inventory of existing IHR-related training activities and materials available (including main topics, available languages and whether the material is available for use by others) will be compiled. A survey amongst partners of possible training offers might be helpful for further definition of training activities. Lead: ISCIII co-lead: SSI, Participation: BMASGK, HCDPC/ KEELPNO, FHI, MS, NIZ-PZH.

Task 8.2. Development of curricula for basic and advanced face-to-face and on-line training

Lead: IPHS, co-lead: RKI, Participants: PHE, MoH-FR, NIJZS, RIVM, ISCIII, HCDPC/ KEELPNO, FHI, NIZ-PZH, MS

The aim of the training will be to strengthen the IHR (2005) core capacities according to country needs.

WP8 will develop a training curriculum and generic module-based basic IHR-training package which can be adapted for different priority regions based on country needs with special emphasis to capacity building of low GNI countries. The training will utilize and build-on existing material from WHO, ECDC and WP8 countries training experience. It will base on the outcomes of subtask 1.2. Training will comprise of both face-to-face trainings and on-line problem-based learning delivered on a learning platform with field exercises and simulations. The sharing of best practices and challenges between countries will be encouraged during trainings. Guidelines for face-to-face and on-line exercises will be developed.

Specific advanced learning modules will depend on the results of the training needs assessment and

Work Package 9: Chemical safety and chemical threats

Start month: 1

End month: 36

Work Package Leader: DH

Task 9.1 Gap analysis

Lead: DH/PHE; Co-Lead: FoHM; Participants: NIJZ, HD, MFH (NAPH, Moldova)

In collaboration with WP5, a fact-finding/gap analysis will be conducted to determine which areas require further action, with a view to strengthen chemical core capacity implementation under IHR.

Task 9.2 Strengthening existing mechanisms

Lead: DH/PHE; Co-Leads: RIVM, NIJZ Participants: MoH-FR, HD

In collaboration with WP4 and WP5, existing mechanisms for chemical incident preparedness, risk communication and operational response will be identified and where necessary strengthened, to promote their uptake by all EU countries.

Task 9.3 Surveillance of chemical incidents

Lead: DH/PHE; Co-Leads: RIVM, HD; Participants: NIJZ, MFH (Malta), NAPH (Moldova)

Under IHR, tested surveillance systems are required for the detection, verification and risk assessment of chemical events of (potential) international health concern as part of a multi-hazard surveillance strategy. As a first step, the benefits of chemical event surveillance, in relation to public health preparedness will be reviewed, and used this as a baseline to inform subsequent activities.

Task 9.4 Training program and materials

Lead: DH/PHE; Co-Leads: IPHS, RKI; Participants: NIJZ, RIVM

In association with other WPs as required, materials will be devised and developed to identify and assess best practices, gaps, bottlenecks and lessons learned from previous events. These will include workshop material and chemical incident exercise scenarios, to be held on areas such as:

- Preparedness of EU MSs to cross-border chemical health threats (according to IHR and Dec 1082/2013) including e.g. continuity planning, intersectoral collaboration

- Surveillance, alerting and notifying of cross-border chemical health threats
 - The rapid risk assessment of chemical health threats
 - Public health response and safety when dealing with/responding to potential chemical health threats
 - Improving access to information on roles and responsibilities of the Commission and other EU organisations
- Material will be prepared for two workshops, to be integrated with existing WP5 and WP8 activities. The developed materials may also be used in other workshops/training activities in the Joint Action to cover chemical threats.

Task 9.5 Exercises

Lead: DH/PHE; Co-leads: IPHS, RKI; Participants: NIJZ, RIVM

In collaboration with WP5 and WP8, WP9 will contribute exercise material to existing WP activities. This will enable WP9 to test current preparedness and response arrangements to a serious cross border threat to health involving chemical and environmental hazards within the scope of IHR and EU Decision 1082/2013/EU.

Task 9.6 Standard Operating Procedures (SOPs)

Lead: DH/PHE; Co-leads: NIJZ, RIVM; Participants: MFH (Malta), NAPH (Moldova)

To ensure a baseline competency among EU MSs on their approach to cross-border chemical health threats and promote sustainability of the outputs of this Joint Action, SOPs will be produced, based on findings from the workshops and the best practices, gaps and bottlenecks identified previously.

Subcontracting

24 - DH will subcontract experts on poison and toxicology for the surveillance and medical management activities.

Work Package 10: Case management and infection prevention and control preparedness

Start month: 1

End month: 36

Work Package Leader: INMI

WP10 activities will strengthen case management and Infection Prevention and Control (IPC) Preparedness in participating countries. The WP contributes to the overall and comprehensive strengthening of the IHR through several activities coordinated and integrated with other WPs:

- Mapping and assessing the existing facilities and country clinical preparedness. The map will inform WP5 and WP6 regarding the clinical capacities and development of preparedness and response tools and indicators.
- The feasibility study for an expert clinical support service will be part of the

workshop with WP5 – (WP5 Task 5.2: International collaboration between authorities during crises)

- The Workshops planned in Task 10.4 will be coordinated together with WP8. The workshop on the syndromic approach will fall in the training activities (WP8) for early recognition of potential case with high-consequence infectious diseases (HCID).

- WP10: Clinical capacity assessment - Linked to WP6 assessment on preparedness, WP10 will benefit of the Disease X scenario (WP6) and will contribute to the clinical and biorisk management of the scenario development

- Interaction with WP7 and laboratory networks, joint participation to workshops and through the collaboration with other WPs in the development of assessment tools.

The following tasks will ensure achievement of the WP objectives:

Task 10.1 Mapping of existing facilities (Lead: SERVAS; Co-Lead: RFL)

Existing Infection Prevention and Control (IPC) facilities will be mapped. Interactive maps will link the geography of communities with availability and accessibility of health services, or disease prevention and control services. The map will provide a comprehensive picture of the expertise for management of HCID.

Task 10.2 Assessment of country hospital preparedness and capacity for HCID, including high isolation clinical centers (Lead: UKF; Co-Lead: INMI; participants: IHUMI)

Based on the Map (Mapping of existing facilities, Task 1), an electronic follow-up by self-assessment questionnaire will be developed and filled by each MS and JA partners.

- Under Task 10.2, two workshops will be organized:

- Workshop 10.2.1 – To define recommendation for assessment (WS arranged by UKF in Germany).

- Workshop 10.2.2 – To discuss recommendation for improvement of the assessed facilities (WS arranged by INMI in Italy)

Task 10.3 Feasibility study for an expert clinical support service for HCID (Lead: HD; Co-Lead: FoHM) This task aims to define the characteristics of an expert clinical consultation and support service. This will result in a set of technical recommendations which would be part of the evaluation in WP5 where identification of key challenges in national and international collaboration between governments and national authorities will be conducted in a dedicated workshop/ exercise.

Task 10.4 Application of a “syndrome based” approach for prompt and early clinical management of HCID (Lead: INMI; Co-Lead: SSI; Participants: VHA, IHUMI, THL) The implementation of this task will be carried out through different phases for identification and management of the HCID.

Under Task 10.4, two workshops will be organized:

- Workshop 10.4.1 – This workshop will involve all SHARP partners and will be focused on the identification of the list of HCID, case definition of each HCID; systematic identification of major disease drivers and threats, and; evaluation of validated severity scores. (WS arranged by INMI in Italy).

- Workshop 10.4.2 – This workshop will involve the dissemination and discussion of the obtained results. (WS arranged by SSI in Denmark)

Subcontracting:

1 – THL will use subcontracting to hire clinical experts from a Finnish infectious diseases hospital for the activities of WP10.

COORDINATOR



TERVEYDEN JA HYVINVOINNIN LAITOS (THL)

MANNERHEIMINTIE 166
00271 HELSINKI
30

Finland

WEBSITE: [http:// www.thl.fi](http://www.thl.fi)

PARTNERS

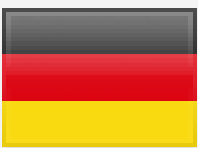


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City: 13353 Berlin

Country: Germany

Website: [http:// www.thl.fi](http://www.thl.fi)



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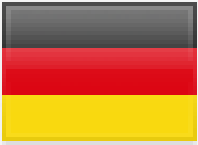
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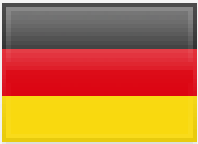


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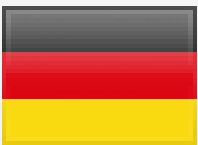
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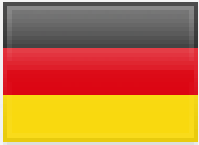
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ISTITUTO NAZIONALE PER LE MALATTIEINFETTIVE LAZZARO
SPALLANZANI-ISTITUTO DI RICOVERO E CURA A
CARATTERESCIENTIFICO
Street: Via Portuense 292
City: 00149 Rome

Country: Italy
Website: [http:// www.thl.fi](http://www.thl.fi)



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.thl.fi](http://www.thl.fi)



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CARATTERESCIENTIFICO
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City: 00149 Rome

Country: Italy
Website: [http:// www.thl.fi](http://www.thl.fi)



BUNDESMINISTERIUM FUER GESUNDHEIT
Street: Radetzkystrasse 2
City: 1030 WIEN

Country: Austria
Website: [http:// www.thl.fi](http://www.thl.fi)



BUNDESMINISTERIUM FUER GESUNDHEIT
Street: Radetzkystrasse 2
City: 1030 WIEN

Country: Austria
Website: [http:// www.thl.fi](http://www.thl.fi)



BUNDESMINISTERIUM FUER GESUNDHEIT
Street: Radetzkystrasse 2
City: 1030 WIEN

Country: Austria
Website: [http:// www.thl.fi](http://www.thl.fi)



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Country: Austria
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Country: Austria

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Street: Radetzkystrasse 2

City: 1030 WIEN

Country: Austria

Website: [http:// www.thl.fi](http://www.thl.fi)



MINISTRY OF CIVIL AFFAIRS

Street: Trg Bosne i Hercegovine 3

City: 71000 SARAJEVO

Country: Bosnia and Herzegovina

Website: [http:// www.thl.fi](http://www.thl.fi)



MINISTRY OF CIVIL AFFAIRS

Street: Trg Bosne i Hercegovine 3

City: 71000 SARAJEVO

Country: Bosnia and Herzegovina

Website: [http:// www.thl.fi](http://www.thl.fi)



MINISTRY OF CIVIL AFFAIRS

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City: 71000 SARAJEVO

Country: Bosnia and Herzegovina

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Street: Trg Bosne i Hercegovine 3

City: 71000 SARAJEVO

Country: Bosnia and Herzegovina

Website: [http:// www.thl.fi](http://www.thl.fi)



HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO
Street: ROCKEFELLER STR. 7
City: 10000 ZAGREB

Country: Croatia
Website: [http:// www.thl.fi](http://www.thl.fi)



HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO
Street: ROCKEFELLER STR. 7
City: 10000 ZAGREB

Country: Croatia
Website: [http:// www.thl.fi](http://www.thl.fi)



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City: 10000 ZAGREB

Country: Croatia
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Country: Croatia
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STATNI USTAV JADERNE, CHEMICKE A BIOLOGICKE OCHRANY vvi
Street: KAMENNA 71
City: 26231 MILIN

Country: Czech Republic
Website: [http:// www.thl.fi](http://www.thl.fi)



STATENS SERUM INSTITUT
Street: Artellerivej 5
City: 2300 Copenhagen

Country: Denmark
Website: [http:// www.thl.fi](http://www.thl.fi)



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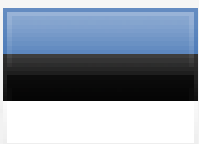
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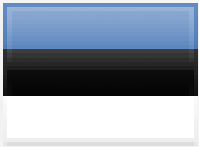
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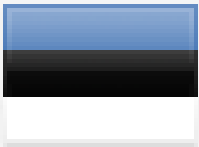
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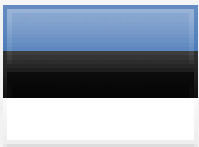
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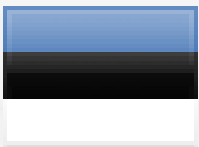
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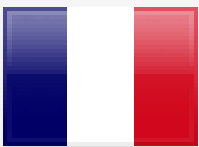
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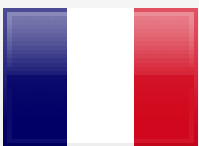
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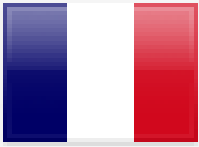
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Street: AVENUE Duquesne
City: 75007 PARIS

Country: France
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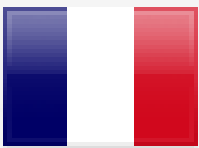
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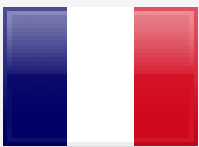
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City: 75007 PARIS

Country: France
Website: [http:// www.thl.fi](http://www.thl.fi)



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KENTRO ELENCHOU & PROLIPSIS NOSIMATON
Street: AGRAFON 3-5
City: 151 23 MAROUSI

Country: Greece
Website: [http:// www.thl.fi](http://www.thl.fi)



ETHNIKOS ORGANISMOS DIMOSIAS YGEIAS
Street: AGRAFON 3-5
City: 151 23 MAROUSI

Country: Greece
Website: [http:// www.thl.fi](http://www.thl.fi)



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Street: AGRAFON 3-5
City: 151 23 MAROUSI

Country: Greece
Website: [http:// www.thl.fi](http://www.thl.fi)



THE NATIONAL PUBLIC HEALTH ORGANIZATION(NPHO)

Street: ΑΓΡΑΦΩΝ 3-5

City: 151 23 MAROUSI

Country: Greece

Website: [http:// www.thl.fi](http://www.thl.fi)



ORSZAGOS KOZEGESZSEGUGYI INTEZET

Street: Anna u. 5

City: 1221 BUDAPEST

Country: Hungary

Website: [http:// www.thl.fi](http://www.thl.fi)



ORSZAGOS KOZEGESZSEGUGYI INTEZET

Street: Anna u. 5

City: 1221 BUDAPEST

Country: Hungary

Website: [http:// www.thl.fi](http://www.thl.fi)



State Emergency Medical service

Street: Laktas Street 8

City: 1013 Rīga

Country: Latvia

Website: [http:// www.thl.fi](http://www.thl.fi)



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City: 1013 Rīga

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LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA

Street: Vilniaus St.

City: 01506 Vilnius

Country: Lithuania

Website: [http:// www.thl.fi](http://www.thl.fi)



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Street: Vilniaus St.

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Street: Vilniaus St.

City: 01506 Vilnius

Country: Lithuania

Website: [http:// www.thl.fi](http://www.thl.fi)



Ministry for Health - Government of Malta

Street: Palazzo Castellania, 15 Merchants Street

City: VLT 1171 Valletta

Country: Malta

Website: [http:// www.thl.fi](http://www.thl.fi)



RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU

Street: Antonie Van Leeuwenhoeklaan 9

City: 3721 MA BILTHOVEN

1

Country: Netherlands

Website: [http:// www.thl.fi](http://www.thl.fi)



RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU

Street: Antonie Van Leeuwenhoeklaan 9

City: 3721 MA BILTHOVEN

1

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City: 3721 MA BILTHOVEN

1

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Website: [http:// www.thl.fi](http://www.thl.fi)



HELSEDIREKTORATE

Street: Universitetsgata 2

City: 0130 Oslo

7000

Country: Norway

Website: [http:// www.thl.fi](http://www.thl.fi)



HELSEDIREKTORATE

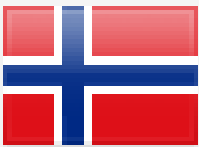
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NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO-PANSTWOWY
ZAKLAD HIGIENY

Street: CHOCIMSKA

City: 00791 WARSZAWA

Country: Poland

Website: [http:// www.thl.fi](http://www.thl.fi)



NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO-PANSTWOWY
ZAKLAD HIGIENY

Street: CHOCIMSKA
City: 00791 WARSZAWA

Country: Poland
Website: [http:// www.thl.fi](http://www.thl.fi)



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MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA

Street: Alameda D. Afonso Henriques 45
City: 1049-005 LISBOA

Country: Portugal
Website: [http:// www.thl.fi](http://www.thl.fi)



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Street: Alameda D. Afonso Henriques 45
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MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA

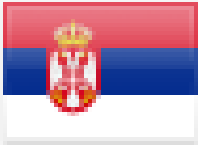
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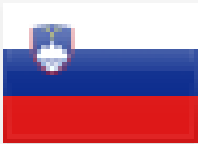
INSTITUT ZA JAVNO ZDRAVLJE SRBIJE 'MILAN JOVANOVIC -
BATUT'

Street: Dr Subotica 5

City: 11000 Belgrade

Country: Serbia

Website: [http:// www.thl.fi](http://www.thl.fi)



NACIONALNI INSTITUT ZA JAVNO ZDRAVJE

Street: TRUBARJEVA

City: 1000 LJUBLJANA

Country: Slovenia

Website: [http:// www.thl.fi](http://www.thl.fi)



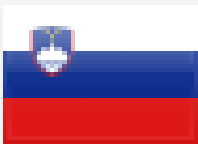
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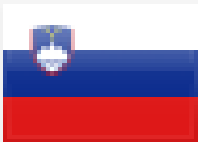
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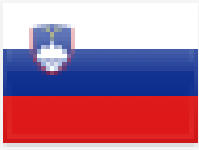
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Street: TRUBARJEVA
City: 1000 LJUBLJANA

Country: Slovenia
Website: [http:// www.thl.fi](http://www.thl.fi)



INSTITUTE DE SALUD CARLOS III
Street: CALLE SINESIO DELGADO 4-6
City: 28029 MADRID

Country: Spain
Website: <http:// www.thl.fi>



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Street: CALLE SINESIO DELGADO 4-6
City: 28029 MADRID

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Street: CALLE SINESIO DELGADO 4-6
City: 28029 MADRID

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Website: [http:// www.thl.fi](http://www.thl.fi)



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Street: CALLE SINESIO DELGADO 4-6
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Street: CALLE SINESIO DELGADO 4-6
City: 28029 MADRID

Country: Spain
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



FOLKHALSOMYNDIGHETEN
Street: SE-17182
City: SE-17182 Solna

Country: Sweden
Website: [http:// www.thl.fi](http://www.thl.fi)



Department of Health
Street: Waterloo Rd
City: SE1 8UG London

Country: United Kingdom
Website: [http:// www.thl.fi](http://www.thl.fi)



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Street: Waterloo Rd
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Country: United Kingdom
Website: [http:// www.thl.fi](http://www.thl.fi)



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Department of Health
Street: Waterloo Rd
City: SE1 8UG London

Country: United Kingdom
Website: [http:// www.thl.fi](http://www.thl.fi)



HEALTH SERVICE EXECUTIVE HSE
Street: Dr Steevens' Hospital
City: DUBLIN 8

Country: Ireland
Website: [http:// www.thl.fi](http://www.thl.fi)



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Street: Dr Steevens' Hospital
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AGENTIA NATIONALA PENTRU SANATATE PUBLICA
Street: Gheorghe Asachi st., 67A
City: MD-2028 Chisinau

Country: Moldova
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Layman report

DH

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/03/2023

Layman report of the final report

Final report

THL

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/03/2023

Final report of the action

A blueprint of dissemination

DH

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/01/2023

A blueprint of dissemination for future Joint Actions

Communication and dissemination report

DH

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/03/2023

Final report of the Communication and dissemination work package

Midterm internal evaluation reports

HCDCP(KEELPNO)

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 30/09/2021

The interim report will serve to fine tune and adjust activities and priorities in the second half of the JA. It will be a formative review of the progress,

achieved up to that point, in relation to budget criteria, quality criteria, time and effectiveness criteria. The report will also provide recommendation for improvements in the second half of the project, where applicable.

Final internal evaluation report

HCDCP(KEELPNO)

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/03/2023

Final evaluation report will include the comprehensive assessment to what extent the aims and objectives are met. It will be a summative review of all activities conducted. The report will examine the project's achievements, vis-à-vis the original planning. The final report will include a tool that can be used to evaluate the project impact beyond its duration (see the WP description).

Final external evaluation report

HCDCP(KEELPNO)

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/03/2023

The final findings of the impact assessment will be reported. It will depict the assessment of the project achievements in relation to the results planned, identify strengths and weaknesses as well as factors that have impeded the achievement of the planned objectives.

Sustainability Report

MOH-FR

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/01/2023

Sustainability Report on SHARP sustainability strategy, that will include for each topic (i.e. each WP) priorities and concrete examples of integration into national plans and for regional organizations, including required training and communication strategies

Reports on improving IHR implementation

FOHM

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/10/2022

Reports on knowledge and practices and added value of external evaluation processes and facilitating strengthening of selected core capacities in the EU and neighboring countries (M43)

Report on international collaboration between authorities during crises

HD

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/01/2023

Report on international collaboration between authorities during crises based on implementation of Task 5.2.

Report on the use exercises and AAR

FOHM

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/10/2022

Report on the use of exercises and AAR as part of monitoring for IHR (2005) core capacities and implementation of Decision 1082/2013/EU at the European level.

Report on lessons learned from Covid-19

RIVM

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 30/06/2022

Report on lessons learned from Covid-19

Report on assurance of high quality of diagnostic

RKI

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/01/2023

Report on assurance of high quality of diagnostics for highly infectious pathogens applied in microbiological laboratories of participating SHARP JA

countries by conducting annual EQAEs.

Report on modern molecular diagnostic methods

INMI

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/01/2023

Report on assessment of and recommendations for application of modern molecular diagnostic methods, including AST

Recommendations for risk management

FOHM

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/01/2023

Recommendations for risk management and risk reduction in diagnostics of highly pathogenic agents.

Final training report

IPHS

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 31/03/2023

Final report on all training provided in WP8, including the training packages and on-line platform

WP9 Final report

DH

Strengthened International Health Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Expected on: 28/02/2023

A report detailing of SOPs; summaries of reports (e.g. on surveillance and training materials); as well as approaches to ensure sustainability.

Report on existing facilities

ISCIII

Strengthened International Health Regulations and Preparedness in the EU -
Joint Action (SHARP JA)
Expected on: 31/12/2021
Report on the assessment of existing facilities, including mapping

Feasibility study report

HD

Strengthened International Health Regulations and Preparedness in the EU -
Joint Action (SHARP JA)
Expected on: 30/09/2022
Report on feasibility study for an expert clinical support service for high-
consequence infectious diseases

Report on syndrome-based approach

INMI

Strengthened International Health Regulations and Preparedness in the EU -
Joint Action (SHARP JA)
Expected on: 30/09/2022
Report on the implementation of a syndrome based clinical protocol

Basic and advanced training curricula

IPHS

Strengthened International Health Regulations and Preparedness in the EU -
Joint Action (SHARP JA)
Expected on: 31/03/2023
Report on curricula developed for basic and advanced face-to-face and on-line
training

Report on SOPs developed

DH

Strengthened International Health Regulations and Preparedness in the EU -
Joint Action (SHARP JA)
Expected on: 28/02/2023
Report on SOPs developed for participating countries

Midterm external evaluation report

HCDCP(KEELPNO)

Strengthened International Health Regulations and Preparedness in the EU -

Joint Action (SHARP JA)

Published on: 14/06/2022

The external evaluators will draft in the middle of the project duration a report stating the progress so far (M32).

Chemical laboratory response network - scoping report

HD

Strengthened International HeAlth Regulations and Preparedness in the EU -
Joint Action (SHARP JA)

Published on: 14/06/2022

A report outlining the desirability and the feasibility to set-up a European
chemical laboratory network to respond to serious chemical health threats.

Review of planning and evaluation tools

RIVM

Strengthened International HeAlth Regulations and Preparedness in the EU -
Joint Action (SHARP JA)

Published on: 22/03/2022

Review of integrated evidence-based planning and evaluation tools and for
Preparedness and Response cycle

Report on training needs

IPHS

Strengthened International HeAlth Regulations and Preparedness in the EU -
Joint Action (SHARP JA)

Published on: 22/03/2022

Report on assessment of the cross-sectoral training needs across countries

Fact-finding report

DH

Strengthened International HeAlth Regulations and Preparedness in the EU -
Joint Action (SHARP JA)

Published on: 22/03/2022

A report detailing the current state of play with regard to cross-border
chemical health threat preparedness at the EU and MS level.

Interim report

THL

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Published on: 04/03/2021

Progress report for the first 18 months of the JA

Leaflet

DH

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Published on: 25/11/2020

Leaflet to promote the action

Website

DH

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Published on: 25/11/2020

A website to inform about and promote the Joint action

Evaluation plan

HCDCP(KEELPNO)

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Published on: 25/11/2020

A developed and approved evaluation plan including objectives, methodology, indicators and time plan. The evaluation plan will be based on a baseline assessment.

Guidance on sustainability

MOH-FR

Strengthened International HeAlth Regulations and Preparedness in the EU - Joint Action (SHARP JA)

Published on: 25/11/2020

Guidance tool to ensure that sustainability is taken into consideration by all WPs throughout the Joint action

WP5 Work plan

FOHM

Strengthened International Health Regulations and Preparedness in the EU -
Joint Action (SHARP JA)

Published on: 25/11/2020

Work plan with selected challenges/gaps in addition to a timeline.