



EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Office of the Chief Scientist

**SPECIFIC AGREEMENT No. 11 /ECD.3511
to the Framework Partnership Agreement No. GRANT/2008/006
ON A GRANT FOR AN ACTION**

This specific agreement ("the agreement") is concluded between:

The European Centre for Disease Prevention and Control (hereinafter referred to as "ECDC" or the "Centre"), which is represented for the purposes of signature of this agreement by Mr Johan Giesecke, Head of the Chief Scientist Office,

of the **one part**,

and

Istituto Superiore di Sanità (ISS), established in Viale Regina Elena, 299 - 00161 Roma, Italy, (VAT No.: IT03657731000) represented by Prof. Enrico Garaci, President, his authorized representative, the partner acting as coordinator of the consortium, (the "coordinator") and the other partners identified in Article I.1.3 of Framework Partnership Agreement No. GRANT/2008/006 signed between the ECDC and ISS,

of the **other part**

Luca Fulginiti
LUCA FULGINITI

HAVE AGREED

The following annexes form an integral part of the agreement:

- Annex A:** Request for technical and budget proposal OCS-12-1151-JGmoca of 31 May 2012.
- Annex B:** Technical and budget proposal submitted by ISS, June 2012.
- Annex C:** Financial statements to be submitted with the technical implementation report

Article 1 – Purpose of the agreement

The agreement is concluded in the context of the partnership established between the parties. It is drawn up in accordance with the relevant terms of Framework Partnership Agreement No. GRANT/2008/006 signed between the ECDC and Istituto Superiore di Sanità (ISS), on 23 December 2008.

The ECDC has decided to award a grant, under the terms and conditions set out in this agreement and the framework agreement, which the partner hereby declares that he has taken note of and accepts, for the action entitled:

“Seasonal Influenza Vaccination Survey, Influenza Season 2011-2012”.

The partner accepts the grant and undertakes to do everything in his power to carry out the action as described in Annex A, in accordance with the terms and conditions of the above-mentioned framework agreement applicable to the implementation of the agreement, acting on his own responsibility.

Article 2 – Duration of the action

The action shall begin on the date of signature of this Specific Grant Agreement (“starting date of the action”)

The action shall last until 28 February 2013.

The period of implementation of the action shall determine the period of eligibility for the ECDC grant.

Article 3 - Financing the action

The total cost of the action is estimated at **EUR 45,015.97** (forty five thousand fifteen Euro / 97 cents), as shown in the estimated budget in Annex II. The estimated budget shall give a detailed breakdown of the costs that are eligible for ECDC funding under the terms of Article II.17 of the framework agreement, of any other costs that the action may entail, and of all receipts, so that receipts and costs balance.

The total eligible costs of the action for which the ECDC grant is awarded are estimated at **EUR 45,015.97** (forty five thousand fifteen Euro / 97 cents), equal the total cost of the action, as shown in the estimated budget in Annex B. Indirect costs are eligible for flat-rate funding of 7% of the total direct costs eligible, subject to the conditions laid down in Article II.17.3 of the framework agreement.

The ECDC shall contribute within the amount of **EUR 39,954.97** (thirty nine thousand nine hundred fifty four Euro / 97 cents), or a maximum of 90% of the estimated total eligible costs indicated above. The final amount of the grant shall be determined as specified in Article II.20 of the framework agreement, without prejudice to Article II.22 thereof.

Article 4 – Payment arrangements

Pre-financing:

Within 45 days of the date when the last of the two parties signs the agreement receipt of the request for pre-financing, a pre-financing payment of **EUR 15,981.99** (fifteen thousand nine hundred eighty one Euro / 99 cents) shall be made to the partner, representing 40% of the maximum amount of the grant specified in Article 3.

Interim payment:

A request for interim payment shall be accompanied by the interim technical implementation report and financial statement specified in Article II.18.3 of the framework agreement, in accordance with the timeline specified in Annex A.

The ECDC shall have 20 days to approve or reject the technical implementation report or to request additional supporting documents or information under the procedure laid down in Article II.18.3. In that case, the partner shall have 20 days to submit the additional information requested or a new report.

The amount of the interim payment shall be determined on the basis of the eligible costs actually incurred, as shown in the interim statement and approved by the ECDC, to which shall be applied the percentage of the ECDC grant specified in Article 3.

The interim payment shall be made to the partner within 30 days following approval by the ECDC of the technical implementation report accompanying the request for interim payment.

The ECDC may suspend the period for payment in accordance with the procedure in Article II.19.2 of the framework partnership agreement GRANT/2008/006

Payment of the balance:

The request for payment of the balance shall be accompanied by the final technical implementation report and financial statement as specified in Article II.18.4 Framework Partnership Agreement – GRANT/2008/006.

The ECDC shall have 20 days to approve or reject the technical implementation report or to request additional supporting documents or information under the procedure laid down in Article II.18.4. In that case, the partner shall have 20 days to submit the additional information or a new report.

A payment representing the balance of the grant determined in accordance with Article II.20 of the Framework Partnership Agreement – GRANT/2008/006 shall be made to the partner within 30 days following approval by the ECDC of the implementation report accompanying the request for payment of the balance.

Article 5 – Submission of reports and other documents

The technical implementation reports, financial statements and other documents must be submitted in English, in accordance to Article 4 (Payment arrangements) or the equivalent article in the framework agreement within 1 month following the closing date of the action specified in Article 2 or before.

SIGNATURES

For the partner
Prof. Enrico Garaci,
President,

For the ECDC
Johan Giesecke,
Head of the Chief Scientist Office,

Signature 

Signature 

Done at ROMA, date 03/08/2012

Done at Stockholm, date 17 Aug 2012

Annex A

9





Istituto Superiore di Sanità
Attn: Dr Fortunato D'Ancona
VENICE II Project Coordinator
CNESPS
Viale Regina Elena, 299
00161 – Roma
ITALY

OCS-12-1151-JGmoca
Stockholm, 31/05/2012

Dear Dr. D'Ancona

Request for technical and budget proposal under the Framework Partnership Agreement – GRANT/2008/006

The ECDC invites the partner acting as coordinator of the consortium and the other partners identified in Article 1.1.3 of Framework Partnership Agreement No. GRANT/2008/006 signed between ECDC and ISS to submit a proposal for carrying out the following activity:

Survey on seasonal influenza vaccination in the EU and EEA/EFTA countries.

The main objective of the survey will be to obtain the vaccination coverage rates for seasonal influenza for 2011/2012 influenza season for both general population and among specific risk and target groups.

Secondary objectives of the survey will be: a) To update available information on country specific influenza vaccination recommendations for different groups; age groups, risk groups, target groups and the general population); b) To update available information on methods used to monitor, calculate, or estimate vaccine uptake for the groups targeted for influenza vaccine; c) to capture relevant data related to the Council Recommendation on Seasonal Influenza Vaccination.

The study will obtain data from all European Union (EU) and European Economic Area (EEA) Member States (MS) for influenza seasons 2010/2011 to compare data with one another between countries and with previous VENICE surveys on the same topic.

The VENICE II project will undertake a web-based survey. The survey (to be carried out before October 2012) will investigate seasonal vaccination coverage for 2011/2012 influenza seasons. The survey will also capture other relevant data related to the Council Recommendation on Seasonal Influenza Vaccination. ECDC will clearly indicate what additional questions should be included in the VENICE survey.

This survey will be a collaborative study between the European Centre for Disease Prevention and Control (ECDC), VENICE II Consortium and European Union (EU) and European Economic Area (EEA) Member States (MS). An additional collaborator is the World Health Organisation (WHO) with whom data will be shared according to their data requests.

It is proposed that the survey would be conducted through gatekeepers, who have been previously identified and are responsible for conducting all VENICE surveys inside their countries.

The results of the survey will also be used in the interim report from the EU Commission to the Council on implementation of the Council Recommendation on Seasonal Influenza Vaccination. The interim report will be coordinated by ECDC.

Expected project's outputs

The deliverable of this grant is a CONFIDENTIAL report that will be provided to ECDC by VENICE.

If and when ECDC uses or shares VENICE generated data or reports with organizations outside of ECDC, these organizations will be required to cite VENICE as the source for these data. ECDC reserves the right to decide about the distribution of data to external partners. Articles and reports that will present VENICE generated data should either include representative VENICE authorship or acknowledge the VENICE source. This will be agreed upon with VENICE consortium as soon as the case arises. Any distribution of collected information or part of it, by VENICE consortium will be only after written authorisation from ECDC.

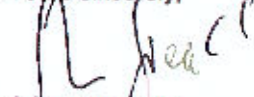
For the required activities, the estimated part of the ECDC financing (maximum 90% of eligible costs) should not exceed EUR 40,000 of ECDC costs.

The implementation of these activities needs to be carried out by Jan 31st, 2013. The implementation applies on the condition that an invoice / request for payment is submitted by 30th of November.

Any request for interim payment shall be accompanied by the interim technical implementation report and financial statement as specified in the Annex VIII b – Estimated unit prices for further activities, on this point please refer to the excel file enclosed.

The amount of the interim payment shall be determined on the basis of the eligible costs actually incurred, as shown in the interim statement and approved by the ECDC, to which shall be applied the percentage of the ECDC, as specified in Article 3 Framework Partnership Agreement – GRANT/2008/006.

Yours sincerely,



Johan Giesecke
Head of the Chief Scientist Office

Enclosed:
Annex VIIIb

Annex B

en





Proposal to ECDC

Seasonal Influenza Vaccination Survey, Influenza season 2011-12

VENICE II Consortium

June 2012

Developed by
Darina O'Flanagan
Suzanne Cotter
Jolita Mereckiene

e

1

f

Background

Epidemics of influenza typically occur during the winter months in temperate regions. Influenza viruses cause disease among all age groups with rates of infection highest among children, but rates of serious illness and death highest among persons aged 65 years and over, children aged less than two years, and persons of any age who have medical conditions that place them at increased risk for complications from influenza. Death is reported in 0.5- 1 per 1000 cases of influenza. The majority of deaths occur in those over the age of 65. Even in winters when the incidence of influenza is low, 3,000 - 4,000 excess deaths may be attributable to influenza in the United Kingdom. Influenza viruses also can cause pandemics when a new influenza virus subtype emerges leading to serious illness among humans and significantly increased mortality. ⁽¹⁾

Seasonal influenza causes significant morbidity with the most frequent complication being pneumonia, most commonly secondary bacterial pneumonia. Primary influenza viral pneumonia is an uncommon complication but is associated with a high death rate. Other complications include worsening of pre-existing chronic medical conditions such as chronic bronchitis or chronic heart failure. ⁽²⁾

Though influenza disease is usually self-limiting, it causes a considerable impact on the individual's daily life, affects the demands for health services and can create economic loss. In a Swedish study undertaken in 2005 (n=121) 67% of respondents aged between 5 and 64 years reported being absent from school or work due to influenza and (n=122) 76% reported having to spend at least one day in bed. ⁽³⁾

The main public health intervention to prevent influenza is influenza vaccination. Currently available influenza vaccines can be expected to provide 70-90% protection against influenza in populations less than 65 years of age. Protective efficacy against infection can be somewhat lower in the elderly with influenza vaccination reducing influenza-associated morbidity by 60% and influenza-related mortality by 80%. ⁽⁴⁾

At European level, there is already a commitment to increase seasonal vaccination coverage in line with EC Council and WHO recommendations. ⁽⁵⁾ There is a need to continue to monitor seasonal influenza vaccine uptake, work which has previously been done through the VENICE network. Therefore, it is proposed that VENICE network should also collect the vaccine uptake for seasonal influenza for 2011-12 influenza season.

VENICE network is ideally placed with its contacts, expertise and infrastructure to assist ECDC in rapidly accessing this information from participating countries in relation to vaccine preventable diseases. Recent experience from the EU funded VENICE project has demonstrated the value in member states sharing general information on vaccination programmes; such as age groups targeted, vaccination schedules used, how the vaccination programmes are delivered, how policy decisions are made (and by whom and using what data), and to identify what policy changes are anticipated within member states. ⁽⁶⁾

The most recent VENICE surveys on the subject of influenza vaccine have proved invaluable in comparing country policies, programmes, and uptake in relation to achieving EU/WHO goals on vaccination uptake in different risk groups. The data obtained from these studies

demonstrated that some countries are already on, or near target, in achieving WHO or EU goals. Information provided in recent studies has provided valuable insight into policies that can achieve higher uptake.^(7;8)

Objectives

The main objective of the survey is to obtain the vaccination coverage rates for seasonal influenza for 2011-12 influenza season for both general population and among specific risk and targeted groups.

Secondary objectives of the survey are:

1. To update available information on country specific influenza vaccination recommendations for different groups: age, risk and targeted groups and the general population;
2. To update available information on methods used to monitor, calculate or estimate vaccine uptake for the groups targeted for influenza;
3. To capture relevant data related to the Council recommendation on seasonal influenza vaccination.

The study will obtain data from all European Union (EU) and European Economic Area (EEA) Member States (MS) for influenza season 2011-12 in order to compare data with one another between countries.

Methods

Study Design

A web-based based survey will be undertaken.

This survey will be collaborative study between the European Centre for Disease Prevention and Control (ECDC), VENICE II Project and European Union (EU) and European Economic Area (EEA) Member States (MS). Each MS previously identified and enrolled gatekeepers/contact points, who are responsible for conducting all VENICE surveys inside their countries. WHO also may be included as collaborating part of this survey.

Currently in the VENICE project there are 27 EU participating countries and also Norway and Iceland. Lichtenstein is not involved in VENICE project.

Data collection

A standard questionnaire will be developed using close-ended questions predominantly. Information will be sought on population groups recommended influenza vaccination (age, occupation, medical or social condition risk), whether countries had mechanisms in place to monitor influenza vaccine uptake and whether uptake was monitored, the method used to monitor uptake, recent vaccination coverage results by population group and season, payment and administration costs for vaccine, health care setting where vaccine was typically administered, methodology used to promote influenza vaccines and how this activity is supported and finally, information will be sought on planned policy or operational changes over the next couple of years.

Data handling

The electronic questionnaire will be developed on VENICE website in August 2012, which will be available for all participating parts (<http://venice.cineca.org>). Electronic questionnaire will be pre-filled and contain data from the latest survey conducted for influenza season 2010-11. Gatekeepers in each country will update this information and will be asked to provide vaccination coverage data for season 2011-12. VENICE project IT people will collate information in to one excel file and will be downloaded by VENICE II project WP4 group.

Data processing

Gatekeepers in each MS will enter data directly on-line. Single data entry will be introduced. WP4 group will contact countries gatekeepers by email or telephone if clarification will be needed to perform validation.

Pilot study

The questionnaire will be pilot tested by five VENICE project-leading partners: Italian Istituto Superiore di Sanita (ISS), the French Institut de la Veille Sanitaire (INVS,) Danish State Serum Institute (SSI), Polish National Institute of Public Health-National Institute of Hygiene and the Irish Health Protection Surveillance Centre (HPSC). The piloting of the study will be undertaken in the second part of July/early August 2012. After the pilot study, the questionnaire will be reviewed and amended as necessary.

Study time

MS will be asked to complete electronic questionnaire in September 2012. The accompanying letter has to follow MS explaining the objectives and rationale of the study.

Data analysis

The data will be analysed using Excel. Data have to be analysed in October 2012 and preliminary report of results will be available by end of November 2012.

The main indicators to be analysed will include:

1. Population groups recommended influenza vaccination (age, occupation, medical or social condition risk);
2. Monitoring of influenza vaccine uptake (by country and methodology);
3. Vaccination coverage results by population group and season;
4. Costs associated with programme and who pays (state or individual) and how this impacts on uptake;
5. Usual venues for influenza vaccination;
6. Methodologies used to promote influenza vaccines and how and who supports this activity;
7. Planned policy or operational changes over the next couple of years.

Expected output

The expected output of this survey will be developing a CONFIDENTIAL technical report which will be available on members' area on VENICE website. The final version of the report will be given to ECDC.

Resources

This fixed amount provided by the grant will cover all costs (project management, quality control, support resources, etc.) and all expenditure (management of the firm, secretarial services, social security, salaries, etc.) incurred directly and indirectly in performance of the tasks which may be entrusted to HPSC (for the duration of the project).

Timetable. Survey for vaccination coverage measurement for seasonal influenza for 2011/2012 influenza season in EE/EEA, 2010

Activity*	2012							2013	
	June	July	August	September	October	November	December	January	February
Commence project									
Prepare draft questionnaire (update)									
Consultation with ECDC/VENICE Consortium members and selected MSs									
Pilot questionnaire									
CINECA work needed to update survey tool on VENICE website									
Distribute questionnaire									
Questionnaires returned									
Data analysis									
Draft report									
Data validation-report sent to MSs									
Prepare final report									
Final report submitted									*

Handwritten marks: a blue scribble and a black signature.

*The timetable of project depends from the date when contract will be signed. It might not be possible to complete the project by end January 2012 if the project does not start very soon. The experience of the VENICE team is that due to holidays being taken over the summer that project timetables may be longer than anticipated.

1. CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005;54(No. RR-8).
2. **Influenza In: Atkinson W, Humiston S, Wolfe C, Nelson R, eds. Epidemiology and Prevention of Vaccine- Preventable Diseases. Department of Health and Human Services, USA, 2000: 231-248.**
3. L Payne, S Kuhlamann-Berenzon, K Ekdahl, J Giesecke, L Hogberg, P Penttinen "Did you have flu last week". A telephone survey to estimate a point prevalence of influenza in the Swedish Population Euro Surveill. 2005;10(12):241-4.
4. **Epidemiology and Prevention of Vaccine Preventable Diseases (The Pink Book). 9th Edition, January 2006. The Centres for Disease Control and Prevention, Atlanta.**
5. **European Commission. Proposal for a Council recommendation on seasonal influenza vaccination. 7-13-2009.**
6. **VENICE website (http://venice.cineca.org/the_project.html).**
7. **Mereckiene J, Cotter S, Nicoll A, Levy-Bruhl D, Ferro A, Tridente G, et al. National seasonal influenza vaccination survey in Europe, 2008. Euro Surveill 2008 Oct 23;13(43).**
8. **Mereckiene J, Cotter S, Weber JT, Nicoll A, Levy-Bruhl D, Ferro A, et al. Low coverage of seasonal influenza vaccination in the elderly in many European countries. Euro Surveill 2008 Oct 9;13(41).**

**VENICE Specific agreement n. 11 Proposal - Seasonal Influenza
Vaccination Survey, Influenza season 2011-12**

Global budget (In EUR)

Expenditures

Direct eligible costs		
E1a. Staff costs	€	35.076,00
E1b. Staff Applicant's contribution	€	4.395,00
E2. Travel and subsistence allowances	€	1.300,00
E3. Equipment	€	-
E4. Miscellaneous Services	€	1.300,00
E5. Subcontracting	€	-
Total for Direct eligible costs	€	42.071,00
Indirect eligible costs		
E7. Overheads	€	2.944,97
TOTAL EXPENDITURE	€	45.015,97

Incomes

I1. ECDC funding request	€	39.954,97
I2. Contribution by applicant	€	4.395,00
I3. Applicant's financial contribution	€	666,00
I4. Income generated by the project	€	-
I5. Other external resources	€	-
I6. Other current funding applications	€	-
TOTAL INCOME	€	45.015,97

F. Di Arcan

er

f

**Annex II B VENICE Specific agreement n. 11 Proposal - Seasonal Influenza
Vaccination Survey, Influenza season 2011-12**

Detailed budget (in EUR)

E1. Staff

Feas

Name of the beneficiary	Function		Nb of persons	Nb of days	Daily rate	Cost
HSE	Epidemiologist	Jolita Marackiene	1	80	€ 345.00	€ 27.600,00
CINECA	Developer		1	30	€ 227.00	€ 5.810,00
Cineca	Research Manager (financial contrib)	L. Demattè	1	2	€ 333.00	€ 666,00
						€
						€
Sub-total				144		€ 35.076,00

Staff Pertaining to National Officials

Name of the beneficiary	Function		Nb of persons	Nb of days	Daily rate	Cost
ISS	Project leader	F. D'Arcana	1	4	€ 260.00	€ 1.040.00
HSE	Senior Researchers	S. Coller	1	5	€ 552.00	€ 2.760.00
HSE	Senior Researchers	D. O. Flanagan	1	1	€ 595.00	€ 595.00
						€
						€
Sub total				10		4.395.00
Total Staff Costs				154		39.471,00

E2. Travel and subsistence allowances

Travel expenses

Name of the beneficiary	Purpose	Means of transport	Place of departure	Nb of trips	Nb of persons	Cost
CINECA				2	1	€ 800,00
						€

Subsistence allowances

Name of the beneficiary	Purpose	Place	Nb of days	Daily rate hotel + daily allowances	Nb of persons	Nb of trips	Cost
CINECA			1	€ 250.00	1	2	€ 500,00
Total Subsistence allowances							€ 500,00
Total Travel & Subsistence allowances							€ 1.300,00

E3. Other cost

Name of the beneficiary	Description	Cost
Total other costs:		€

E4. Miscellaneous Services

Name of the beneficiary	Description	Cost
ISS	Consumables & Supplies	€ 800.00
HSE	Consumables & Supplies	€ 500.00
Total Consumables & Supplies:		€ 1.300,00

E5. Subcontracting

Name of the beneficiary	Function	Nb of persons	Nb of days	Daily rate	Cost
					€
Total Subcontracting:					€

E6. Reserve for unexpected costs

	Cost
4.98%	€
Total	€

E7. Overheads

	Cost
7.00	€ 2.944.97
Total	€ 2.944,97

GRAND TOTAL

€ 45.015,97

H. S. Arcana

e

f

VENICE Specific agreement n. 11 Proposal - Seasonal Influenza Vaccination Survey, Influenza season 2011-12

Influenza season 2010-11
Estimated Budget by Beneficiary (in EUR)

Expenditures	Main beneficiary							
	Name of the organisation	Total	ISS Italy	HSE Ireland	NPHL-PZH Poland	INVS France	SSI Denmark	Cineca Italy
Direct eligible costs								
E1a. Staff costs not pertaining to national officials		35.076,00	-	27.600,00	-	-	-	7.476,00
E1b. Staff Pertaining to National Officials		4.395,00	1.040,00	3.355,00	-	-	-	-
E2. Travel and subsistence allowances		1.300,00	-	-	-	-	-	1.300,00
E3. Other cost		-	-	-	-	-	-	-
E4. Miscellaneous Services		1.300,00	800,00	500,00	-	-	-	-
E4 Miscellaneous Services/Audit		-	-	-	-	-	-	-
E5. Subcontracting		-	-	-	-	-	-	-
E6 Reserve for unexpected costs 0%		-	-	-	-	-	-	-
Total for Direct eligible costs		42.071,00	1.840,00	31.455,00	-	-	-	8.776,00
Indirect eligible costs								
E7. Overheads		2.944,97	126,80	2.201,85	-	-	-	814,32
Total - Expenditure		45.015,97	1.966,80	33.656,85	-	-	-	9.390,32

Incomes	Main beneficiary							
	Name of the organisation	Total	ISS Italy	HSE Ireland	NPHL-PZH Poland	INVS France	SSI Denmark	Cineca Italy
Status of the organisation								
1. ECDC funding request		88,76%	47,18%	90,03%	-	-	-	92,91%
2. Contribution pertaining to national officials		39.954,97	926,80	30.301,85	-	-	-	8.724,32
3. Applicant's financial contribution		4.395,00	1.040,00	3.355,00	-	-	-	-
4. Income generated by the project		666,00	-	-	-	-	-	666,00
5. Other external resources		-	-	-	-	-	-	-
6. Other current funding applications		-	-	-	-	-	-	-
Total - incomes		45.015,97	1.966,80	33.656,85	-	-	-	9.390,32

F. A. M. M. M.

ee

[Signature]