

# **TWINNING INTERIM QUARTERLY REPORT**

No. 6

**ANNEX**

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**Annex 1      Minutes 5<sup>th</sup> Steering Committee**

**5<sup>th</sup> Meeting of the Steering Committee**

**Minutes**

**Date:** 9 June 2006 (12.00-13.20)

**Place of meeting:** Ministry of Health, Limbová 2, 837 52 Bratislava, room no. 152/3

**Participants**

• **Present:**

Mr Geert van Etten – Dutch Project Leader (NSPOH) [chair]  
Ms Anne Maria Aalders – RTA (NSPOH)  
Ms Zuzana Krištúfková – Project Manager (PHA SR Bratislava)  
Ms Jana Bosá – Co-ordinator component II (PHA SR Bratislava)  
Mr Milan Nikš – Co-ordinator component III (PHA SR Bratislava)  
Ms Soňa Gabčová – Task manager, Office of Government of SR  
Ms Linda Winklerová – MoH of SR  
Ms Jana Ráčková – RTA Assistant

• **Absent:**

Ms Zuzana Škublová – Slovak Project Leader (MoH of SR)  
Ms Mária Avdičová – Co-ordinator component I (RPHA Banská Bystrica)  
Ms Jana Minarovičová - National Contact Point for Twinning, Office of the Government of SR  
Mr Miroslav Škvarka - CFCU at the Ministry of Finance of SR  
Ms Martina Galabová - CFCU at the Ministry of Finance of SR  
Mr Steef van den Berg – Royal Netherlands Embassy  
Ms Magdaléna Čáčová – Section of Public Health at the MoH of SR  
Ms Elena Marušáková – PHA SR Bratislava

**Agenda**

**1. Opening**

Mr van Etten as the chairperson officially opens the meeting and introduced agenda. Ms Škublová and Ms Avdičová were apologized for their absence.

**2. Discussion on 5<sup>th</sup> Quarterly report**

Mr van Etten informed that the second phase of the project has been finished and now the third phase is starting, which is very promising.

**Component I**

Mr van Etten asked Ms Aalders whether there are any updates on extra activity 1.12 (1-day ENTERNET workshop) as because all other activities concerning this comp. I have been planned. Ms Aalders informed that it was already decided to organize the activity in week 36, presumably at the beginning of the week. She also mentioned continuing discussion whether beside STE Mr van Pelt also second expert will come. Ms Krištúfková reminded that originally it was planned that two STEs will come but CFCU refused to accept this. Ms Aalders informed that after this SC meeting a separate meeting with Ms Krištúfková will take place to clarify the idea of this activity.

## Component II

Mr van Etten informed that in general, all three STEs involved in activity 2.5 were very satisfied with the good progress in this component and had a big appreciation for what had been done until now.

Mr van Etten put forward his comment to the mission report of Ms Adamčáková who made the study visit to the Netherlands. He informed that NSPOH will contact the laboratory in Rotterdam where she did her internship to clarify the miscommunication about the “learning objectives” that were sent to the head of laboratory in Rotterdam already a long time ago but the people in the laboratory were not informed enough. But this issue has to be solved between the NSPOH and laboratory in Rotterdam and has nothing to do with the Slovak partners.

Mr van Etten asked Ms Bosá for the date of the second inspection by SNAS. Ms Bosá explained that the reconstruction of the second part of laboratory area is currently starting. For this reason it is not a good time for the second visit of SNAS. Therefore Ms Bosá asked them for possibility to postpone the inspection to September because of the installation of the new laboratory equipment and solving of non-conformities (air-conditioning etc.) which can be solved only by mentioned reconstruction. Secondly, SNAS is not making partial visits but should only come after the overall removal of all non-conformities. Ms Bosá estimated the end of reconstruction for the middle of September after the second SNAS inspection will take place. Mr van Etten asked when we can expect the final result of the accreditation process. Ms Bosá did not know exactly but maybe a few days/weeks after this second visit. She hopes to receive the certificate before the end of the project.

Mr van Etten mentioned the issue of a laboratory IT system / software which seem to be a very crucial thing for the laboratory work. It is important to have identified this problem and then search for solution and financial sources. Ms Bosá reminded that she already asked for financing such laboratory software but unfortunately not successful until now.

Ms Bosá came up with the proposal of cancelling the visit of STE Mr Galama (activity 2.6 planned from 10-12 July) if that is possible. The reason for this is the planned reconstruction of the lab area (1<sup>st</sup> July – mid Sept) which seems not to be the right time for such a visit because everything will be damaged. Beside this she also did not see any chance of postponing this mission because of the end of the project in October. Ms Aalders informed that it might be difficult to cancel Mr Galama's visit because he is combining this activity with his work for other TW light project and his flight ticket has been already booked. Ms Bosá suggested that it would be possible to organize for him a trip to laboratories at Regional PHAs in Banská Bystrica and Košice. This issue will be discussed later in coming days by RTA and the comp. coordinator.

## Component III

Ms Aalders and Mr van Etten assess the situation that most of the work in order to implement the external quality had been done. Mr Nikš clarified that he prepared everything important related to this component but the description of the activities does not reflect to the actual situation. Mr Nikš explained that already in January it was decided of having two schemes. One scheme is for public health system where measles, mumps & rubella and poliomyelitis were done; problem is only with influenza. Second scheme is for salmonellosis and resistance to antibiotics where the target group was specified – more than 50 laboratories in whole Slovakia. The external control had been done and it only needs to be evaluated. The only question is how to evaluate it, describe it in English.

Mr van Etten suggested that Mr Nikš together with Ms Aalders will rewrite the text on page 12 of the 6<sup>th</sup> Quarterly report / Component III. Mr van Etten also suggested rewriting the first sentence on page 5 of the report / Mandatory results / Component III. See *conclusions*.

Mr van Etten opened the discussion on issue of co-financing part, also mentioned on page 17 under Issues. He expressed his concerns that there is a serious problem while preparing the workshops. According to the twinning manual and the twinning contract, the expenditures

related to organizing workshops (catering ...etc) and other project events / meetings should be financed by the national authority. Based on the latest information this kind of expenditures were financed from the private pocket of the CCs, PM or RTA which is unacceptable. Mr van Etten would like to put forward this problem to Ms Škublová or her boss if necessary in order to find some solution for future activities. He experienced in other projects that usually Ministry of Finance send some money to Ministry of Health who may subsequently allocate them to the Public Health Authority. It is not clear how these things should work here in Slovakia and who is responsible. *See conclusions.*

Mr van Etten informed that regarding the expenditure only 60% to 70% of the total budget is expected to be spend. He suggested mentioning this in this report under Section 3: Expenditures.

Because Ms Škublová had been ill for a long time and did not comment the 5<sup>th</sup> Quarterly report, it is decided to wait for her comments for incorporation till the end of next week (16<sup>th</sup> June). *See conclusions.*

#### Conclusions:

- Mr Nikš and Ms Aalders will rewrite the text of the 6<sup>th</sup> QR on page 12 / Comp. III as well as page 5 Mandatory results / Comp. III.
- Mr van Etten will try to contact Ms Škublová in the matter of co-financing project workshops.
- Ms Škublová will give her comments to the 5<sup>th</sup> QR till 16<sup>th</sup> June.

### **3. Discussion on Action plan**

There were no comments to the Action plan.

### **4. Discussion on finalization of the project**

Mr van Etten gave the floor to Ms Aalders to explain the proposal of finalization of the project. Ms Aalders introduced the proposal (see annex to this minutes). 31<sup>st</sup> of October is the official end of the project. There are still lots of activities to take place until middle of September. There are also following reports to be written and approved by the Steering committee: 6<sup>th</sup> Quarterly report, 7<sup>th</sup> Quarterly report (will cover activities in September) and the Final report. Therefore Ms Aalders would like to plan and make sure that everything will be finished in time and approved of by middle of October because the CFCU has asked for this.

Participants of the SC agreed to have the next meetings as follows:

- 6<sup>th</sup> SC meeting for the 6<sup>th</sup> QR on 8<sup>th</sup> September 2006 at 12 hrs
- 7<sup>th</sup> SC meeting for the 7<sup>th</sup> QR and the Final report on 5<sup>th</sup> October 2006

*See conclusions.*

Ms Aalders informed about the new format of the Final report. She will organize a separate meeting with SK-PI, PM and CCs to discuss in more detail how everyone should participate in writing the Final report. *See conclusions.*

Ms Aalders raised the issue of having a "Closing ceremony" which is usually organized at the end of the project. Ms Gabčová also mentioned that usually the Ministry involved is organizing this event. Mr van Etten continued with this idea and proposed to have such a final ceremony "De-kick-off meeting". The ceremony should be organized for wider audience and with speakers who will provide them with the final results from the project. The responsibility for organizing should be up to the Ministry of Health of SR. Ms Aalders added that this is not a job for RTA but the PM, CCs and MoH should come with this idea and be responsible. Ms Bosá said that it is also the question of money which is very important. Ms Krišťúfková prom-

ised to discuss this issue with Ms Škublová, the director of PHA in coming week. See *conclusion*.

Conclusions:

- 6<sup>th</sup> SC meeting for the 6<sup>th</sup> QR will take place on 8<sup>th</sup> September 2006 at 12 hrs.
- 7<sup>th</sup> SC meeting for the 7<sup>th</sup> QR and the Final report will take place on 5<sup>th</sup> October 2006.
- Ms Aalders will organize in near future a separate meeting with SK-PI, PM and CCs discussing the Final report.
- Ms Krištůfková will try to discuss the issue of “Closing ceremony” with Ms Škublová and the director of PHA in coming week.

**5. Any other business**

Ms Krištůfková put forward a new request to be financed by saved money from RTA absence – translation of a website. She explained that because of the newly developed software for infectious diseases, it will be useful if some standard reports will be translated into English to enable also people from other countries to read it and get some information on the situation in Slovakia. Mr van Etten suggested to take-up this issue with Ms Škublová and CFCU and if all parties will agree it can be arranged. He awarded that the issue should be clear very soon because for the previous similar proposals the decision making and approving took approx. 4 months. Therefore if there are still any other new proposals from CCs or PM there should be a fixed deadline of its latest submission. See *conclusions*.

Ms Aalders asked Ms Krištůfková to put the idea of English translation of some parts of the web site on paper and afterwards this will be forwarded to Ms Škublová. This also applies for any other new proposals. See *conclusions*.

In case that Ms Škublová will not be back in her office next week, RTA office will send all necessary documents on Monday 12 June (especially the Side letters no. 8, 9 and 10) to her assistant Ms Winklerová to be printed out and forwarded to Ms Škublová’s home for her signature. Otherwise the Side letters will be signed only by RTA and forwarded directly to the CFCU for approval because the documents are already waiting to be signed for almost 3 weeks now. See *conclusions*.

Conclusions:

- RTA office will send on Monday the 12 of June the Side letters no. 8, 9 and 10 (and other important documents if any) to Ms Winklerová to arrange the signature of Ms Škublová in case of her continuing absence in her office.
- The deadline for submission of any other new proposals for using the extra RTA money is 1<sup>st</sup> July 2006.
- Ms Krištůfková will write down the idea of English translation of the website to be forwarded to Ms Škublová the coming week.

**6. Date of next meeting**

The tentative date of next meeting is agreed on 8 September 2006 at 12.00 hrs.

**7. Closure**

Mr van Etten officially thanks all participants for their co-operation and contribution. He concluded that the Steering Committee approved the 5<sup>th</sup> Quarterly report and the Action plan and agreed on dates of next meetings of the committee. Ms Škublová’s comments to the 5<sup>th</sup> QR will be incorporated as agreed under point 2.

**Annex 2      Minutes 12 / 07 / 2006**

**Minutes  
of the meeting to the project 2003-004-995-03-07 Strengthening the Surveillance and  
Control of Communicable Diseases in the Slovak Republic**

Date: 12 July 2006  
Place: Public Health Authority of the Slovak Republic, meetingroom of the Director of PHA SR  
Present: Mr. František Valášek, Mrs. Zuzana Škublová, Mrs. Zuzana Krištúfková, Mrs. Mária Avdičová, Mrs. AnneMarie Aalders, Mrs. Jana Račková, Mrs. Jana Bosá, Mr. Ivan Oravský, Mrs. Soňa Kalnická, Mrs. Elena Marušáková  
Agenda: 1. Development in the project and ensuring its finalization within the planned schedule.  
2. Ensuring the sustainability of the project.

Add 1)

- 1.1. Mr. František Valášek informed that the reconstruction works at the Section of Medical Microbiology at PHA SR which are essential for installation of the machines delivered within the project (delivery company Vitrum) will be finished until the end of the September. Presumptive cost of the reconstruction is approx. 4 mil SKK. The reconstruction will start immediately after the contract is signed on 12.7.2006 with the budget of a 4 mil SKK. This amount should be sufficient in case of no other unforeseen circumstances.
- 1.2. Mrs. Avdičová informed that trainings within the component I have been started. The work runs according the schedule. The pilot run is planned to start on 13<sup>th</sup> of July 2006. Unfortunately, the configuration of the hardware needed for the pilot run of the software did not take place. The adjustment made by the supplier (Tempest) would cost approx. 38.000 SKK because according to the supplier, this would be an extra work beyond the contract. RPHA in Banská Bystrica is not able to solve the situation by their staff. The configuration will be carried out by the company Tempest beyond the contract, what will entail not calculated additional costs for RPHA Banská Bystrica. Mr. Valášek requested Mrs. Krištúfková to have a meeting on the level of representatives of suppliers (Tempest, Softec) to discuss operational necessities. It is important to subsequently inform the Director of PHA SR about the results and possible requirements.
- 1.3. This meeting was organized with the initiative of Mrs. Škublová considering that the project is approaching its end and therefore it will be necessary, for the final report, to summarize the results and impacts of the project on the recipient as well as sustainability of the project in the future.  
In this sense she asked present coordinators of components to make an evaluation:
  - Component II – coordinator of comp. II Mrs. Jana Bosá (Head of the Section of clinical microbiology, PHA SR):  
The evaluation according to her consists of 2 parts – a) laboratory equipment and b) accreditation of NRCs.
    - a) According to the coordinator, the chosen way for supplying of the equipment was not the best one, even in spite of the fact that procurement went in accordance with valid rules and Phare procedures. One company delivering all equipment has been selected. Later there was a need to sign an addendum to the contract. At the end, the representative of the company had been changed. Coordinator of this component made an oral agreement with

the former representative of the company concerning the installation of the equipment. Due to the change on the position of the representative, these agreements might not have to be fulfilled by the company (installation of air-conditioning as a bonus plus to the equipment ... etc.).

In the contract, there is a length and way of service as well as the demand for a service department in the Slovak Republic. As far as it is known, the company still does not have such a department in Slovakia. The delivery of the equipment at Public Health Authority of the Slovak Republic in Bratislava has not been completed and installed due to the inadequate laboratory area. In accordance with the contract, the whole delivery and installation has to be finished till 30<sup>th</sup> of September 2006. This could be endangered if the essential reconstruction of concerned laboratory area will not be finished (see 1.1.). Regional PHA in Banská Bystrica and in Košice received and installed all laboratory equipment as stated in the contract. Only the installation of 1 autoclave in Banská Bystrica and 1 autoclave in Košice did not take place because of missing plugs. The autoclaves are stored in the premises of these Regional PHAs). The installation was supposed to take place after ensuring needed plugs and should be for free as it was orally agreed between the former representative of the company and the coordinator.

As a follow up of above mentioned unsolved problems, it was agreed that Mrs. Bosá will ask Mrs. Škublová by an official letter to arrange an official meeting with the company Vitrum Bratislava, s.r.o.

- b) Accreditation was planned to take place in 9 NRCs (7 in Bratislava, 1 in Banská Bystrica and 1 in Košice) – in total around 30 methods. NRCs in Banská Bystrica and in Košice have been accredited, that means methods for diphtheria and pertussis.

NRC for arboviruses and viruses of haemorrhagic fever was not established (the assumption of its establishment was included in the original project aim). Nowadays it exists only as a laboratory and is placed in the identical lab areas as NRC for Influenza. The work is performed by Mrs. Blaškovičová and 1 laboratory technician, also the diagnostics and isolation of virus of tick encephalitis is performed there. From the perspective of material-technical, the conditions of establishing planned NRC are present but in the present days it is not possible to create it due to the personnel reasons.

Financial analysis needed for the reconstruction of the lab area includes PHA SR, Regional PHA in Banská Bystrica and Regional PHA in Košice. Banská Bystrica and Košice did received required sufficient finances, but PHA SR did not. The finances were allocated also because of the control by ECDC related to the preparedness of the Slovak Republic for potential pandemic flu. Therefore PHA SR is starting the reconstruction only now.

Accreditation by SNAS at PHA SR was because of above mentioned reconstruction works postponed to September 2006.

- Component III – realization of external quality (Mr. Nikš), reported by Mrs. Jana Bosá. External control took place on each planned workplaces, providers and suppliers with whom the cooperation is active. Mr. Nikš is preparing the pilot project. If this project will be accepted, it will become a standard part of the work also when the project is finished.
- Component I – software for epidemiologist, reported by Mrs. Avdičová. She repeated that the work runs according the schedule (see 1.2.). She informed that previously oral promise of the company Softec to develop software also for the laboratories is being moved by the company beyond the signed contract with request of additional financing. Mrs. Avdičová also informed that the originally signed contract within the project is not ensuring an up-grade of the software. Also there are no other budgeted financial resources for that.

- 1.4. Final report should include all recommendations given by the experts during the whole run of the project. The recommendations should be listed together with their non-/acceptation by the recipient institution (PHA SR). If they were not accepted, there should be reason “why”. The report should be based on the Action plan that is updated by Mrs. Aalders.

- 1.5. Related to the necessity to realize some planned activities to the end of the project, it was agreed that PHA SR will ensure related additional costs for 2 workshops with duration of 5 days and potentially for the final conference as far as they can pay for it. Concerning the final conference which is not originally planned in the project, the MoH SR will ensure the printing of invitations and other materials. The question of translation and its financing is still unclear. MoH SR offered their premises which mean no additional expenditures for renting different room. Mrs. Škublová asked the representatives for their cooperation while preparing the final conference.

Add 2)

- 2.1. All participants agreed on the fact that it is very important to prepare such steps that will guarantee sustainability of the project for the future. Subsequently the Director of PHA SR asked for immediate reassessment, consulting and calculation of all needful additional costs needed to ensure the proper functioning of the project outcomes in the future, within the standard working of PHA SR and Regional PHAs. This has to be submitted to the Director and the Head of Economy Department at PHA SR with the deadline of 22<sup>nd</sup> July 2006.
- 2.2. Director of PHA SR said that for ensuring proper functioning of the developed software it is needed to build a virtual network connecting PHA SR to all Regional PHAs in Slovakia. This idea was supported by other participants (Mrs. Krištúfková, Mrs. Avdičová). The director informed that the meetings took place and contracts with company Slovanet are under preparation. Company Slovanet has a material-technical and personnel conditions which means that it is able to build such a virtual network over the whole Slovakia for the purposes of PHA SR and Regional PHAs. Unfortunately, some Regional PHAs (Trnava ... etc.) are not accepting this idea and it is not possible to force them, as an independent legal subjects. Virtual network is needful also because of crucial exchanging of professional data and is preparing in a way to allow have a net-meetings and video-conferences. Additionally, the summary costs for unified network will be lower than the costs for individual local networks with not guaranteed safe and correct data transmission. Local providers that could be cheaper and could provide faster connection are not able to build virtual network covering the whole Slovakia because of the lack of technical-material (routers ....etc.) and personnel resources.

Bratislava, 19.7.2006

Written by: Mrs. Elena Marušáková

Verified by: Mrs. Zuzana Škublová

From the Slovak original translated to English by Mrs. Jana Ráčková, RTA Assistant.

**Annex 3      Minutes Monthly meeting 08 / 08 / 2006**

**Monthly meeting 4/2006**

**Minutes**

**Date:** 8<sup>th</sup> of August 2006

**Place of meeting:** Ministry of Health, Limbová 2, 837 52 Bratislava, room No. 105

**Agenda:**

- I.      Conclusions from previous Monthly meeting
- II.     Evaluation and progress of following projects:
  1.      2003-004-995-03-07 Strengthening the Surveillance and Control of Communicable Diseases in the Slovak Republic,
  2.      2003-004-995-03-06 Strengthening of Statistics Health Information System and its Harmonization with EU Requirements,
  3.      2003-004-995-01-06 Improved Access to Health Care for Roma Minority in the Slovak Republic.
  4.      2003-004-995-01-04 Strengthening of Human Resources and Implementation of EU Methodology for Surveillance of Human Enteroviruses in the Slovak Republic
  5.      TR/05/015 Increasing Safety, Quality and Availability of Organs, Tissues and Cells for Transplantation in the Slovak Republic.
- III.    Other
- IV.    Conclusions

**Participants:**

Mrs. Zuzana Krištúfková – Project manager, project no. 1  
Ms. Annemarie Aalders – RTA, project no. 1  
Ms. Jana Ráčková – RTA Assistant, project no.1  
Ms. Soňa Gabčová - Task manager, Government Office SR  
Mr. Miroslav Škvarka – Task manager, Central Finance and Contracting Unit  
Ms. Silvia Rusznyaková – Department of National Fund, Ministry of Finance SR  
Ms. Shubhada Bopegamage – Project manager, project no. 4, Slovak Medical University  
Ms. Jana Motusová – Slovak Medical University  
Mr. Daniel Kuba – deputy Project manager, project no. 5, Slovak Medical University  
Ms. Iveta Krbaťová – Project Unit of Foreign Aid, Ministry of Health SR  
Ms. Zuzana Škublová – Senior Program Officer, Ministry of Health SR  
Ms. Linda Winklerová – Project Unit of Foreign Aid, Ministry of Health SR

**Not present:**

Mr. Peter Tatár – Project manager, project no. 3, Ministry of Health SR  
Mr. Lubomír Vlčák – Project manager, project no. 2, Institute of Health Informatics and Statistics (IHIS)  
Ms. Martina Galabová – Task manager, Central Finance and Contracting Unit

**Add I.)**

- The meeting with the representatives of the PHA was held on 12.7.2006 in order to discuss problems regarding refreshment for participants of the project activities, organizing the final conference and sustainability of the project results.
- In connection to project 2003-004-995-03-06 Strengthening of Statistics Health Information System and its Harmonization with EU Requirements, the Final conference was held on

14.7.2006. The representatives of National Centre of Health Information (former IHIS), SOFTEC company and Ministry of Health were present. All participants of the project expressed their satisfaction with the project and evaluated it as very successful.

- The Work plan and budget of the project TR/05/015 Increasing Safety, Quality and Availability of Organs, Tissues and Cells for Transplantation in the Slovak Republic was sent to CFCU as required.

## **Add II.)**

### **1. Strengthening the Surveillance and Control of Communicable Diseases in the Slovak Republic**

Ms. Škublová informed about personal changes in directory of Public Health Authority. Mr. Rovný was appointed to Chief Hygienist position again. Therefore another meeting of experts relevant to the project with the representatives of PHA is planned. It will be held on 9<sup>th</sup> of August 2006 at 9:30 a.m. At this meeting several issues will be discussed: ensuring of the refreshment for participants of project activities, new technical and financial issues and results of the project – if directory is satisfied with them and their sustainability. Then Ms. Škublová asked Ms. Krištúfková to inform about particular components of the project.

Ms. Krištúfková reminded, that project consisted of three components: Twinning, Supply of HW and laboratory equipment and Development of SW. She informed that there were some problems with components 2 and 3.

#### I. component: Twinning

In connection to Twinning, Ms. Krištúfková informed that from 3<sup>rd</sup> of July until 4<sup>th</sup> of July the activity 1.11 had been realized at Ministry of Health. It was seminar for 15 epidemiologists from regional public health institutions. All participants were very satisfied with it. The second part of the training is planned on September and it will be held also at Ministry of Health. More than 100 participants are expected to come and they will discuss on the topic how to improve surveillance of salmonellosis in Slovak republic compared with Netherlands.

Ms. Škublová asked if all activities would be finished until the end of the project, because in last quarterly report there had been some time delays mentioned. Ms. Aalders confirmed that all activities would be finished in time.

Ms. Škublová further informed that despite of Final conference was not considered as regular activity, both parties had decided to organize it. It is planned to be held on 5<sup>th</sup> of October 2006. Some preliminary steps have been already done. Ministry of Health will offer its own premises. Ms. Krištúfková should prepare rough calculation of refreshment costs. Two TWL experts will come to present actively on the final conference, and therefore a side letter will be prepared to address this modification in the end of August or in the beginning of September. The CFCU had already agreed with the aim of the Side letter.

#### II. component: Supply of HW and laboratory equipment

Ms. Krištúfková informed that the reconstruction of the laboratories in Bratislava should be finished until the end of the September and then the laboratory equipment should be delivered. The problem with the trainings for staff can arise, because the original contract duration (with Vitrum company) is only until the end of September 2006.

Ms. Škublová informed that delivery of laboratory equipment had been divided into three parts. First of them was delivered in February 2006, second part was delivered but not installed yet. The problem can arise just with third part, which should be delivered only after the end of reconstruction. Ms. Škublová informed that also this issue would be discussed at the meeting with Mr. Chief Hygienist.

#### III. component: Development of SW

The company SOFTEC, s.r.o. is developing new software for communicable diseases reporting. The SW should be able to evaluate data and produce some reports and analyses. According to information

of Ms. Hrubá, who is responsible for this component, SW is still not ready for pilot testing. Ms. Krišťúfková informed that despite of representatives of SOFTEC were working hard and they were introducing new version of SW every day, it still had a lot of mistakes.

Ms. Škublová informed, that representatives of SOFTEC company would be present at the meeting with Mr. Chief Hygienist, which was planned on 9<sup>th</sup> of August. She suggested preparing the list of problems, which would be discussed at the meeting with them. The deadline for development of SW is September 2006. Ms. Krišťúfková informed that prolongation would be very helpful.

## **2. Strengthening of Statistics Health Information System and its Harmonization with EU Requirements**

The project consists of three components. Two components are already concluded. The last unfinished component is Development of SW. According to wording of director of National Centre for Health Information, he is very satisfied with project. On 14<sup>th</sup> of July the Final conference was held and SW was introduced there. Presently the Interim reports No.2 and 3 also with final report are being finalized.

## **3. Improved Access to Health Care for Roma Minority in the Slovak Republic**

In the frame of this project two components are still unfinished. They are: delivery of the educational tools (films and brochures) and terrain health workers system. Regarding the films and brochures the deadline of delivery was shifted until the end of July. Company EUROFINANC requested another prolongation for next 3 weeks. This request was denied by Ministry of Health. The films were already presented to the representatives of MoH and other external experts. Presently, EUROFINANC is incorporating the comments and remarks of relevant experts to the film scripts and brochures and finalizing them.

In connection to terrain health workers system Ms. Škublová informed that meeting of representatives of MoH and management of the EuroPlus Company had been held. The previous problems were solved. All reports are now prepared and submitted as requested by MoH. Ms. Gabčová asked if some changes had been made in the management of the project. Ms. Škublová answered that not, but it had been intended to ensure external monitoring to control activities right on the place of their realization. Regarding the website of the project, Ms. Škublová informed, that during the previous week the texts and basic framework were submitted to PUFA, which already reacted. Then the basic website will be published, but it will be continuously filled by agreed texts. Ms. Škublová informed also about the dolls (and equipment) – MoH will require information from terrain health workers how they use them. The manuals for terrain health workers were finalized during July and they are ready for printing. According to information of Ms. Škublová, EuroPlus supported by MoH will ask CFCU for Addendum to the contract to support previous training activities for terrain health workers – the first training should be held in the end of August.

## **4. Strengthening of Human Resources and Implementation of EU Methodology for Surveillance of Human Enteroviruses in the Slovak Republic**

Ms. Škublová informed that despite of the TW team effort, the prolongation of the project wasn't approved. This information was announced officially by letter of Ms. Czuczurová, who is director of CFCU. She asked all parties to summarize project documentation and to prepare final report. Ms. Bopagamage told, that she hadn't obtained the official information about the end of the project – she had been informed just by the mail sent by Ms. Galabová. Ms. Bopagamage said, that she had prepared the presentation of the project, addressing mistakes that occurred during the project implementation. Ms. Bopagamage gave her presentation. She promised to send it to relevant institutions (MoH, CFCU, Office of Government).

Ms. Bopagamage stressed, that Slovak Medical University didn't agree with not approving the prolongation. She asked to whom (in Slovak Republic or also in Brussels) could she address her request for revision of the CFCU decision. Ms. Krbat'ová reminded, that the contracting parties are CFCU and

Dutch partners – so only they could ask for revision. Ms. Gabčová suggested that she would ask Ms. Minarovičová (Slovak NCP for Twinning) if there was any possibility to change actual status quo.

## **5. Increasing the Safety, Quality and Availability of Organs, Tissues and Cells for Transplantation in the Slovak Republic**

Ms. Škublová informed that TW contract was sent to Brussels. The statement of European Commission is expected in September or October 2006, so project activities probably would have to be shifted (the planned start was in September 2006).

In connection to RTA assistant procurement, Ms. Škublová informed that Terms of Reference were translated into English language to allow Italian partners send their remarks. Then ToR was transformed to the form required by CFCU. After some adjustments it will be published in website of Ministry of Health (for 4 – 6 weeks), at [www.profesia.sk](http://www.profesia.sk) and it will be also sent to some translation agencies. The applicants will be required to send whole documentation in hard copy and electronic version in both Slovak and English languages. The Slovak project team in cooperation with Italian partners will do the selection.

### **Add. III.)**

- Ms. Gabčová informed that PHARE Management Committee was held in Brussels and all project in the frame of Transition Facility 2006 were approved. Official information from Office of Government will be delivered.
- Mr. Škvarka informed that he will circulate the TF 2005 projects only in September this year.

### **Add. IV.)**

- The meeting of experts relevant to the project will be held with new Chief Hygienist in order to discuss several actual issues and problems on 9.8.2006.
- SL approving STE for final conference will be sent to CFCU in the end of August or in the beginning of September.
- In connection to the project *Improved Access to Health Care for Roma Minority in the Slovak Republic* PUFA will consider the external monitoring to control activities right on the place of their realization.
- MoH will require information from terrain health workers how they use the dolls (and equipment) for health education.
- EuroPlus supported by MoH will ask CFCU for Addendum to the contract to support previous training activities for terrain health workers.
- Ms. Bopegamag will send her presentation to relevant institutions (MoH, CFCU, Office of Government).
- Ms. Gabčová will ask Ms. Minarovičová (Slovak NCP for Twinning) if there is any possibility to change actual status quo of the project *Strengthening of Human Resources and Implementation of EU Methodology for Surveillance of Human Enteroviruses in the Slovak Republic*.
- PUFA will publish ToR for RTA assistant procurement at the website of MoH, at [www.profesia.sk](http://www.profesia.sk) and will inform translation agencies about it.

**Annex 4      Side letter No. 10**

**SIDE LETTER No. 10**

**TO TWINNING CONTRACT 2003-004-995-03-07/0001  
“Strengthening the surveillance and control of Communicable  
Diseases”**

Twinning No. SK/03/IB/SO/01

Both Twinning partners have agreed the following:

**Art. 1 Objective**

The objective of this Side letter is to appoint Mrs Willy-Anne van Stiphout as expert for the remaining two days of activity 1.11 in July (article 4. Tasks of Annex I), replacing Mrs Aura Timen who is no longer able to complete this activity because of her workload in the Netherlands. The proposed expert has the same qualifications and field of expertise, being specialised in Infectious Diseases Control and providing training in this field. (CV in annex 1, part of this side letter).

**Art. 2 Modification**

In Art. 5 (Human Resources) and Art. 6 – Work schedule.

The expert Timen for activity 1.11 is partly replaced by expert van Stiphout; the fee will remain 450 euro for each working day. The replacement of Mrs Timen by Mrs van Stiphout has no implications for the budget.

**Art. 3 Confirmation of validity**

All of the parts and dispositions of the initial Twinning Contract 2003-004-995-03-07/0001 and the approved side letters or addenda which are not modified here remain valid.

Read and approved for the parties of the Twinning Project:

For Mr. Geert van Etten, Project Leader  
Annemarie Aalders, RTA

Ms. Zuzana Škublová  
Project Leader

**Annex 1: CV Mrs van Stiphout**

**CURRICULUM VITAE**

Proposed role in the project: Training expert for Infectious Diseases control

1. Family name: van Stiphout
2. First names: Willy-Anne
3. Date of birth: November 21<sup>st</sup>, 1956
4. Nationality: Dutch
5. Civil status: cohabiting
6. Education:

<b>Institution</b>	<b>Date: from (m/y) to (m/y)</b>	<b>Degree(s) or Diploma(s) obtained</b>
Catholic University Nijmegen (St Radboud University Medical Center), Nijmegen	Sept 1975 – Oct 1982	MD
Erasmus University, Rotterdam	Feb 1983 – Nov 1986	PhD
Netherlands School of Public Health, Utrecht	1994 – July 1996	Social Medicine / Community Health

7. Language skills (5=excellent, 4=good, 3=satisfactory, 2=fair, 1=weak for competence)

<b>Language</b>	<b>Reading</b>	<b>Speaking</b>	<b>Writing</b>
Dutch	Native		
English	5	5	5
German	3	2	1

8. Membership of professional bodies:
  - Vereniging voor Epidemiologie (Netherlands Epidemiological Society),
  - NVAG (Netherlands Society for medical doctors working in public health policy, management and research)
9. Other skills; (e.g. Computer literacy, etc): Computer literate
10. Present position:

<b>Company/location</b>	<b>Position</b>	<b>Description</b>
A: STIP (Stiphout Training in Practice), Zweeloo	Trainer	MD in Social Medicine, teacher in epidemiology
B: NSPOH	Trainer	Teacher in epidemiology

## 11. Years within the firm:

A: 4,5 (since October 2000)

B: 15 (since 1990, parttime)

## 12. Key qualifications (relevant to the project):

Since 1989 teaching epidemiology to all kinds of medical doctors and workers in Public Health, including international students

## 13. Specific experience abroad:

<b>Country</b>	<b>Date: from (m/y) to (m/y)</b>	<b>description</b>
Europe	1983-2000	-European Society of Cardiology, Working Group on Epidemiology and Prevention
Europe	1983-2001	-International Society and Federation of Cardiology, section on Cardio-vascular Epidemiology and Prevention
USA and Europe	1989-	-International Epidemiological Association
Europe	1993-	-European Public Health Association
Latvia	Sept 2004 – August 2005	NSPOH; Twinning project on Surveillance & Control of Communicable Diseases

## 14. Other professional experience record:

<b>Date</b>	<b>Company/location</b>	<b>Position and description</b>
Dec 1989 – June 1995	GGD (Regional Public Health Service) Bergen op Zoom	Senior epidemiologist
July 1995 – sept 1997	CBS – (Central Bureau of Statistics)Voorschoten	Senior epidemiologist, manager death certificate registration and co-worker on development Dutch HIS/HES combination
Oct 1997 – Oct 2000	ZON (now ZonMw: Netherlands Organisation for Health Research and Development) – Den Haag	Manager Cure and Care Programme

15. Other:

- Publications (including 1 thesis, 16 papers in international peer-reviewed journals, 18 in Dutch peer-reviewed journals, 17 reports, 15 papers in Dutch (medical) journals, 36 (inter)national abstracts, 32 (inter)national presentations, chapters in 4 Dutch medical books and author of Q&A in Dutch epidemiological textbook; list available on request)

16. Contact Address in the Member State, including telephone, fax and e-mail

dr. Willy-Anne H.J. van Stiphout

Klooster 5

7851 AH Zweeloo, The Netherlands

Tel: +31 (0) 591 – 377 725

Fax: +31 (0) 591 – 377 720

E-mail: stipdot@xs4all.nl

**Annex 5      Report Mrs. van Stiphout - activity 1.11**

## **Twinning Project**

Twinning No. SK03/IB/SO/01

### **Strengthening the Surveillance and Control of Communicable Diseases**

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## **MISSION REPORT**

**EXPERT NAME** Mrs. Willy-Anne H.J. van Stiphout, MD, PhD

**COMPONENT** 1

**ACTIVITY NO.** 1.11

**DATES OF VISIT** 2-4 July, 2006

#### **Activities according to the Work Plan**

Original activity during mission: two days workshop on outbreak management for regional staff with exercise on case control and cohort study. Because this activity was not completed, and because it became clear that training in basic epidemiological principles was needed. Together with the Slovak coordinators it was therefore agreed that the 1 day workshop (from 2-4 July) for act. 1.11 will be mainly concerned with basic epidemiological principles.

#### **Summary discussed items (bullets)**

- Types of epidemiological studies and their outcomes (RR, RD/AR, OR) and how they relate to each other. Pro's and con's of the different types, also presented in written material.
- Fundamentals of data analysis: precision and validity
  - Precision is about random error: instead of calculating p-values it is advised to calculate 95% confidence intervals (formula's were given)
  - Validity is about systematic error: it is recommended to separate confounding (bias) from information- and selection bias
- Controlling or adjustment for confounding, depending on how much time is left:
  - Learn to reason in what direction the outcome measure will change after adjustment
  - Learn to calculate an adjusted outcome measure through stratified analysis and standardization was not discussed anymore because of lacking time, but participants were given a copy of the presentation.

#### **Persons met**

<b>Name</b>	<b>Position</b>
See the list of participants from 3 July, 2006	
See the list of participants from 4 July, 2006	

#### **Conclusions (bullets)**

It was difficult to find out which subjects discussed were really new and what was already known, because the participants didn't react to my questions on this matter. However some participants showed in the exercises that they had more knowledge than others. But I do

think issues on effect modification were new for every-one.  
 Also applying the theory into practice (i.e. on the abstracts handed out during the workshop) was really appreciated and very necessary as well. But practising more will still be needed to fully understand the concepts and how to use them.  
 Using a foreign language (English) was an extra “handicap”; some people decided not to attend the second part of the workshop on Tuesday. On the other hand communication went better once one was “used” to it for a longer time. And some participants thought it to be something “extra” to discuss the subjects in English.

Overall, at the end I got the impression that the training was useful for most of the participants but until the end it was not easy to get a good discussion going. In making exercises they were very active however.

#### Recommendations (bullets)

More training on the subjects discussed, with a lot of examples and exercises, will be needed.  
 It is therefore recommended to repeat the issues on data analysis (validity) during the next training in September by way of some exercises.  
 It should also be considered whether simultaneous translation would be helpful or not.

#### Follow-up by RTA (bullets)

#### Remarks (bullets)

#### Evaluation (bullets)

Positive	Negative
1	1
2	2
3	3

Date/signature of Expert	Date/signature of Component co-ordinator	Date/signature of Adviser
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## Lists of participants of the workshop 03 / 07 / 2006

## PREZENČNÁ LISTINA

Workshop Epidemiologické princípy a štatistická významnosť

Miesto konania: MZ SR Bratislava, miestnosť č. 152/3

Čas: 3.7. 2006 13,00 -17,00 hod

P.č.	Priezvisko a meno	Pracovisko	Podpis
1.	Willy-Anne van Stiphout	Holandsko	<i>Willy-Anne van Stiphout</i>
2.	Bakoš Ivan, MUDr.	RÚVZ Spišská Nová Ves	<i>Bakoš Ivan</i>
3.	Boledovičová Jana, RNDr.	SZU Bratislava	<i>Boledovičová Jana</i>
4.	Kollárová Jana, MUDr.	RÚVZ Košice	<i>Kollárová Jana</i>
5.	Krajčíková Katarína, Mgr.	ÚVZ SR Bratislava	<i>Krajčíková Katarína</i>
6.	Krištúfková Zuzana, MUDr.	SZU Bratislava	<i>Krištúfková Zuzana</i>
7.	Laifrova Miroslava, MUDr.	RÚVZ Bratislava	<i>Laifrova Miroslava</i>
8.	Lančová Jarmila, MUDr.	ÚVZ SR Bratislava	<i>Lančová Jarmila</i>
9.	Lokša Pavol, MUDr.	RÚVZ Banská Bystrica	<i>Lokša Pavol</i>
10.	Máderová Eva, Doc. MUDr. CSc.	ÚVZ SR Bratislava	<i>Máderová Eva</i>
11.	Rimská Miroslava, Mgr.	SZU Bratislava	<i>Rimská Miroslava</i>
12.	Striežová Eva MUDr	RÚVZ Žiar nad Hronom	<i>Striežová Eva</i>
13.	Šašalová Martina, RNDr.	Železničný zdrav. ústav BA	<i>Šašalová Martina</i>
14.	Štefkovičová, MUDr. PhD, MPH	RÚVZ Trenčín	<i>Štefkovičová</i>
15.	Šuleková Iveta, MUDr.	RÚVZ Galanta	<i>Šuleková Iveta</i>

Hostia:

16.	RAČKOVÁ JANA	ÚVZ SR BA - Praha	<i>Ráčková Jana</i>
17.	Anna Balabeková	ÚVZ SR BA - Praha	<i>A. Balabeková</i>

## Lists of participants of the workshop 04 / 07 / 2006

## PREZENČNÁ LISTINA

Workshop Epidemiologické princípy a štatistická významnosť

Miesto konania: MZ SR Bratislava, miestnosť č. 152/3

Čas: 4. 7. 2006 8,30 – 14,30 hod.

P.č.	Priezvisko a meno	Pracovisko	Podpis
1.	Willy-Annvan Stiphout	Holandsko	<i>W. Stiphout</i>
2.	Bakoš Ivan, MUDr.	RÚVZ Spišská Nová Ves	<i>Ivan Bakoš</i>
3.	Boledovičová Jana, RNDr.	SZU Bratislava	<i>Jana Boledovičová</i>
4.	Kollárová Jana, MUDr.	RÚVZ Košice	<i>Jana Kollárová</i>
5.	Krajčíková Katarína, Mgr.	ÚVZ SR Bratislava	<i>K. Krajčíková</i>
6.	Krištúfková Zuzana, MUDr.	SZU Bratislava	<i>Z. Krištúfková</i>
7.	Laifrova Miroslava, MUDr.	RÚVZ Bratislava	<i>M. Laifrova</i>
8.	Lančová Jarmila, MUDr.	ÚVZ SR Bratislava	<i>J. Lančová</i>
9.	Lokša Pavol, MUDr.	RÚVZ Banská Bystrica	<i>P. Lokša</i>
10.	Máderová Eva, Doc. MUDr. CSc.	ÚVZ SR Bratislava	<i>E. Máderová</i>
11.	Rimská Miroslava, Mgr.	SZU Bratislava	<i>M. Rimská</i>
12.	Striežová Eva MUDr	RÚVZ Žiar nad Hronom	<i>E. Striežová</i>
13.	Šašalová Martina, RNDr.	Železničný zdrav. ústav BA	<i>M. Šašalová</i>
14.	Štefkovičová, MUDr. PhD, MPH	RÚVZ Trenčín	<i>Š. Štefkovičová</i>
15.	Šuleková Iveta, MUDr.	RÚVZ Galanta	<i>I. Šuleková</i>

Hostia:

16.	RAČKOVÁ JANA	ÚVZ SR BA - Phare	<i>J. Račková</i>
17.	A. Apaldem	ÚVZ R Plave	<i>A. Apaldem</i>

**Annex 6      Report Mr. Otto – activity 1.13 (1<sup>st</sup> part)**

## **Twinning Project**

Twinning No. SK03/IB/SO/01

### **Strengthening the Surveillance and Control of Communicable Diseases**

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## **MISSION REPORT**

**EXPERT NAME** Matthias Otto PhD DSc

**COMPONENT** 1

**ACTIVITY NO.** 1.13 (part 1)

**DATES OF VISIT** July 09 – July 14, 2006

#### **Activities according to the Work Plan**

- ☐ Implementation, testing and evaluation of the new system on data collection in 5 selected pilot regions.
- ☐ *Specific requirements from component co-ordinator: To read and comment the last version of the “Proposal on the new software solution EPIS” created by the SOFTEC company.*

#### **Summary discussed items (bullets)**

This activity was aimed at the implementation, testing and evaluation of the new system on data collection (developed by Softec) in 5 selected pilot regions.

Implementation: on arrival, a beta version of the software for the forthcoming information system (“new EPIS”) on communicable diseases (CD) was available.

Testing and evaluation: this was performed in two ways.

- 1) training course in Bratislava (July 10 – 12, 2006): instead of visiting 5 pilot regions, the course organized by Softec (see below) offered a good opportunity to meet representatives from 5 pilot regions and together with them to test basic functionalities of the software.
- 2) Visit to RPHA Trencin (July 13-14, 2006): here a test and evaluation from the user’s perspective at this location was possible.

Ad 1)

The training took place between July 10 – 12, 2006 in a computer training room at the Faculty of Construction of the Slovak Technical University (ul. Karvasa 1, Bratislava). It was organized and executed by SOFTEC representatives. Trainees came from RPHA Banská Bystrica (component 1 coordinator M. Avdicová, F. Hrubá), RPHA Trencin, RPHA Martin, RPHA Rimavská Sobota, RPHA Bratislava-City and UVZ SR Bratislava (about 25 participants in total, most if not all being experienced and familiar with the old EPIS & ISHEM system). A detailed training manual in Slovak language was handed to the participants at the beginning of the course.

Training and evaluation were split into several parts:

Monday, July 10, 2006:

- general introduction
- technical requirements at the user's location
- menu and types of windows
- report of a case of infectious disease, structure of the patient's record
- open cases & processed cases
- case classification
- assignment of cases to epidemics

Tuesday, July 11, 2006

- incoming bulk reports of influenza and flu-like diseases
- processing of incoming bulk reports, weekly reports at the level of a district and a region,
- check for missing bulk reports
- graphical visualization (trends, maps etc)
- messages of the Early Warning system (kinds of messages, creation, weekly reports)

Wednesday, July 12, 2006

- processing of incoming results from laboratories of clinical microbiology
- assignment to cases
- management of contacts
- management of decisions

As stated above, the course served a dual purpose: firstly to become acquainted with the components of the new information system and secondly to test it, to detect errors and malfunctions. The (highly complex) software package is still in a stage of development. It did not undergo a critical revision by Dr. Avdicová & Dr. Hrubá prior to the training course. Thus, quite a number of missing or erroneous functionalities were observed during the three training days. They comprise e.g. non- or malfunctioning menus, missing data (most important: codes of physicians, not yet available from UZIS Bratislava), missing checks of integrity and plausibility, errors in certain workflows and errors in some graphic representations). The participants of the course will prepare an exhaustive list and forward it via Dr. Hrubá to SOFTEC representatives.

Some remarks of more general nature with respect to the training course have to be made:

- just 2 trainees shared one PC which is quite a good ratio
- sufficient time was given to the trainees to explore the new system on an individual base
- the training manual had been didactically well structured

Some circumstances had a less favourite impact on training:

- the information system was still in a stage of development (see above), not really suitable yet for testing by pilot regions and training.
- access to the database was granted using identical login data for all participants, thus it was not possible to explore different roles and functions (physician, RPHA employee, local/regional level etc)
- data entries often could not be checked for correct range(s) and/or plausibility
- the principal menu offered the full scale of features including those which are reserved for administrative purposes (instead of a subset of features assigned to a defined role/function)
- in some menus buttons and/or scrolling did not work yet
- the training took place under hardly acceptable conditions with respect to climate (room temperature exceeding 35 deg C at noon).

While acknowledging the high degree of complexity of the database and the tight time schedule for software development, it would nevertheless have been highly advisable to install the system at RPHA BB prior to pilot training and to test main features in close collaboration with the component 1 coordinator (Dr. Avdicova) and Dr. Hrubá (responsible for IT services).

Certain issues have been discussed but have not yet solved or are to be implemented in the near future:

- secure data transmission ( https protocol)
- construction of a virtual private network
- server operation (versioning, backup, SMS gateways etc)
- help desk/hotline, user administration
- creation of the web portal both for the public health service (discussion forum) and the general public

ad 2)

On July 13 and 14, the RPHA at Trenčin was visited. In several meetings with Dr. Stefkovicová and her colleagues (1 IT specialist and 2 ladies dealing with epidemiological data processing) local working conditions (access to the internet, speed/bandwidth, virtual private network etc) were discussed and the new software tested – this time from the user's perspective at the place of work. In general, the results correspond to those obtained during the Softec course. In addition, several issues of management and practical workflow such as login data administration, data backup, secure data transmission were discussed.

<b>Persons met Name</b>	<b>Position</b>
Dr. Annemarie Alders	RTA
Mgr. Jana Racková	RTA assistant
Dr. Maria Avdicova	Head of the Dept. of Epidemiology, RPHA SR Banska Bystrica
Dr. Frantiska Hrubá	Head of the Dept. of Informatics and Health Statistics, RPHA SR Banska Bystrica
Dr. Zuzana Kristufkova	Head of the Dept. of Control of Infectious diseases, Natl. PHA SR, Bratislava
Ing. L. Sesera	SOFTEC Bratislava
Ing. Mackay	SOFTEC Bratislava
Ing. K. Hierweg	SOFTEC Bratislava
Dr. M. Stefkovicová	RPHA Trenčin
participants of the training course	see list

### **Conclusions (bullets)**

Training was provided on a rather early version of the forthcoming system. However, basically the training course served its purpose: to introduce the new information system to its potential users (from 5 pilot regions) and – at the same time - to detect errors, missing functions and malfunctions.

All notes and suggestions will be sent to Dr. F. Hrubá who will pass them to SOFTEC for correction. In view of the training of regular users starting on July 24, 2006 this issue is of top priority to guarantee a good acceptance of the system.

Note for next course: the training facilities should be equipped with suitable air condition !

### Recommendations (bullets)

- install a help desk / hotline to answer emerging problems (preferentially at RPHA Banská Bystrica)
- Consider a “train-the trainer” approach to educate well-experienced people at each RPHA which in turn may help in the case of local problems.
- Create a discussion forum on technical issues on the portal.
- Put a FAQ-list on the portal
- Consider an evaluation of the training course ( e.g. by means of a questionnaire)

... to be continued after part 2...

### Follow-up by RTA (bullets)

### Remarks (bullets)

### Evaluation (bullets)

#### Positive

- 1 good computer equipment in the training room
- 2 learning-by-doing approach
- 3

#### Negative

- 1 missing air condition in the training room
- 2
- 3

Date/signature of Expert	Date/signature of Component co-ordinator	Date/signature of Adviser

**Annex 7      Report Mrs. de Schipper – activity 2.6 & 3.3**

## **Twinning Project**

Twinning No. SK03/IB/SO/01

### **Strengthening the Surveillance and Control of Communicable Diseases**

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## **MISSION REPORT**

**EXPERT NAME C.J.W. de Schipper**

**COMPONENT 2 and 3**

**ACTIVITY NO. 2.6 and 3.3**

**DATES OF VISIT 11 – 16 June 2006**

#### **Activities according to the Work Plan**

2.6 Development and implementation of the quality control systems.

3.3 Development of Standard Operational Procedures based on the new implemented quality assurance system

#### **Summary discussed items (bullets)**

Activity 2.6 Evaluation of resolving process of non-conformities that were found during the SNAS visit.

- Quality Manual
- Reconstruction (tour of the lab.)
- Customer feed-back
- Internal auditing
- Quality manager
- Solving of other nonconformities (NCF)
- Timeschedule of reconstruction and visit for verification of NCF by SNAS
- NCF's and timeschedule accreditation Kosice and Banska Bystrica

Activity 3.3 Proposal on evaluation of implemented external quality assurance system (EQAS).

- Clarify the match between ongoing activities and requirements of component 3 regarding EQAS (see Annex: Explanatory document activity 3.3)
- Producing a format for evaluation of EQAS results for the project (see Annex: Explanatory document activity 3.3)
- Evaluation of progress of EQAS

<b>Persons met</b>	
<b>Name</b>	<b>Position</b>
Ms Jana Bosa	Comp. Co-ordinator 2 (PHA SR Bratislava)
Mr. Niks	Comp. Co-ordinator 3 (PHA SR Bratislava)
Ms Jana Rackova	RTA assistant
Ms Anne Maria Aalders	RTA

**Conclusions (bullets)****Activity 2.6**

- Chapter 4 of the quality manual is only partially rewritten yet but it is clear what to describe to resolve the NCF's of SNAS. Suggestions for description in the quality manual on five parts of the standard are left with Ms. Bosa.
- Main focus between last visit and now has been on the reconstruction which will be carried out during summer. It was a great achievement of Ms. Bosa that the improvement and money finally got allocated. The plans are clear and contractors are being hired.
- Customer feed-back questionnaires have been produced and send out. Already 80% of are returned and the results are helpful for improving the services. The respondents generally are content with the supplied services of the laboratory. It is good to have this contact with customers.
- It might be more efficient to perform vertical audits in stead of audit by chapter of the standard. Suggestions are already send to Dr. Bosa. The NCF's in this matter have not been solved yet.
- Ms Bosa agrees that being head of the laboratory together with being a Quality Manager is too much. She will be looking into the possibilities to appoint a Quality Manager. This can only take effect after the project finishes.
- Most of the operational NCF's at the workfloor are solved, depending on reconstruction issues. About 20% of the NCF's on documentation are solved, depending on time to address them. Ideas on how to solve the NCF's are clear. Ms. Bosa did not have time yet to look into the suggestions and examples yet regarding management of complaints, checklists for training of employees, vertical audits and management review which were send by me in May.
- It was agreed with the SNAS that they will carry out the verification visit in September after the reconstruction. Ms. Bosa will make time during summer to finalise the required descriptions in Quality Manual and other SOP's for solving the NCF's. Everything should be ready at the time of my next visit beginning of September so I can make last suggestions before the SNAS verification visit. I also can be contacted for advise by mail.
- The solutions for NCF's of Kosice are send to the SNAS, most were on documentation. The verification visit of the SNAS is expected anytime. Banska Bystrica has already received the new certificate.

**Activity 3.3**

- For all schemes carried out, at least first draft SOP's are written. Because the EQAS will not be included in the accreditation this is acceptable. With reaching the Benchmark of the production of the SOP's for the EQAS schemes component 3 formally is finished.
- ATB susceptibility: Since 2002, 15 rounds have been carried out. The samples are send to around 50 clinical laboratories all over Slovakia. The goal of the rounds is mainly educational. New guidelines and insights in the area of ATB susceptibility are communicated and evaluated through these rounds.
- Salmonella scheme has started in 2006. The samples are send to around 50 clinical laboratories. Data of this first round are evaluated. The laboratories participate on a voluntary base but the compliance was 100%. This round addresses a need for communication and education, eventhough the clinical labs send samples for further identification to the reference center for more specific diagnosis. Data of this first round have been evaluated and reported.
- Virological schemes Poliomyelitis are started in 2005 and for Measles and Rubella in 2006. The purpose mainly being standardization of the process. The samples are send to the regional PHA's in Banska Bystrica and Kosice. Data of this first round have been evaluated and reported. There are only two regional PHA laboratories.

They are both included in the rounds. Future considerations might involve finding other ways to guarantee the quality of the work done in the regional PHA's because it is a lot of effort for only two regional laboratories. An alternative for the regional PHA's might be to join in with the international quality control schemes. This will be expensive, maybe it is possible to split samples or to alternate between regional PHA's.

- Crucial for the assurance of the process in the virological workplaces is the standardizing and central producing of cellcultures in PHA Bratislava which has been accomplished.

#### Other

- It was agreed that Ms de Schipper will perform in september activity 2.7 and 3.4 combined during 5 working days, including visits to Kosice and Banska Bystrica.

### Recommendations (bullets)

#### Component 2

1. Make a strict time-schedule up for solving of NCF's before evaluating mission (activity 2.7) in September and make use of mailcontact with expert in preparation for verification visit of SNAS.

#### Component 3 (after finish project)

1. Include SOP's in system of document control. Eventhough the EQAS is not accredited it will be good for evaluating and monitoring the EQAS.
2. Evaluate the effort/benefits of organizing EQAS rounds for two regional PHA.

### Follow-up by RTA (bullets)

### Remarks (bullets)

### Evaluation (bullets)

#### Positive

- 1 Concrete tasks to perform
- 2
- 3

#### Negative

- 1
- 2
- 3

Date/signature of Expert	Date/signature of Component co-ordinator	Date/signature of Adviser

## **Annex to the Mission report of Mrs. de Schipper**

### **EXPLANATORY DOCUMENT ACTIVITY 3.3**

#### **Establishing External Quality Assessment Schemes (EQAS), Public Health Authority of the Slovak Republic (PHA SR)**

##### **Introduction**

Part of the European Twinning project “Strengthening the surveillance and control of Communicable Diseases” is component 3. The goal of component 3 is to implement an external quality assurance in selected areas. As a final benchmark new Standard Operating Procedures for external quality control are to be operational in 5 pilot regions.

There are not five but only two regional PHA’s (Banska Bystricka and Kosice) performing tests within the scope of the NRC’s within the project.

All NRC’s are active in networks for international quality control. The purpose of the EQAS included in the project is interlaboratory quality control at a national level.

The NRC for antibiotic resistance has already implemented EQAS since 2002. This scheme is used as an example for setting-up other EQAS. The different schemes follow the international standard ILAC G13. The EQAS is not part of the accreditation of the NRC’s because the PHA SR is not officially designated to do so by Slovakian law. Also accreditation is not common yet at European EQAS organisations such as the Dutch SKML.

##### **Goal of the PHA SR EQAS**

The PHA SR EQAS is intended to improve and to standardize selected diagnostic procedures in defined fields of clinical and environmental microbiology in the Slovak Republic through monitoring of the laboratory testing performance and education.

##### **Responsibilities working group**

- Dr. Jana Bosá, Quality Manager; responsible for correct realization of individual steps according to international standards and monitoring of progress of the project.
- Dr. Nikš (ATB), Dr. Gavačová (Salmonellosis), Dr. Tietzová (MMR), Dr. Blaškovičová (Influenza), Dr. Sobotová (Polio); responsible for preparation of individual working procedures.
- Dr. Tietzová (Cellculture); responsible for production of standardized cell cultures.

##### **Scope of the PHA SR EQAS**

The PHA SR EQAS can be divided in bacteriological and virological schemes.

###### Bacteriological schemes

The bacteriological rounds are prepared by the NRC’s of the PHA of Bratislava and sent to about 56 clinical laboratories in the SR.

1. antibiotic susceptibility testing of clinical bacterial isolates (ATB susp.)  
4 rounds/year
2. detection, identification and subtyping of *Salmonella* spp. (*Salmonella*)  
1 round/year

###### Virological schemes

The virological rounds are interlaboratory rounds prepared by the NRC’s in Bratislava and sent to the regional PHA’s of Banská Bystrica and Kosice.

1. typing and subtyping Measles

2. typing and subtyping of Rubella
3. typing and subtyping of Poliomyelitis  
1 round/year

#### **NRC's included in the project but not involved in EQAS schemes**

- Typing and subtyping of Influenza virus.  
The typing is not performed by clinical laboratories. The regional PHA's of Banska Bystrica and Kosice only perform screening and send the samples for further diagnostics to the NRC in Bratislava and through them into the international network. To prepare samples for EQAS for influenza is complicated. Carefull consideration is required if setting up a round for the screening of influenza for two regional PHA's is worth the effort.
- Isolation and identification of Neisseria meningitides  
This test is not often performed. The clinical laboratories perform only the basic biochemical identification. All typing and subtyping and susceptibility testing is done in the NRC of Bratislava and discussed in the international network.
- The detection of mumps is used as an screening test for differential diagnosis for measles and rubella. It is not a disease that has to be monitored within the PHA SR.
- Diphtheria diagnostics is only performed in the NRC in Kosice who relate to the international network, so no interlaboratory EQAS within the SR is necessary.
- Pertussis and parapertussis diagnostics is only performed in the NRC in Banska Bystrica who relate to the international network, so no interlaboratory EQAS within the SR is necessary.

#### **Required SOP's**

General:

- Organisation and structure of PHA SR EQAS

Separate SOP's per scheme:

- Sample aliquotting, packing and shipment
- Collection and characterization of samples
- Sample selection and definition of question asked
- Sample producing
- Data collection and preliminary report
- Data analysis, final report.

#### **Conditions**

- There are no sanctions for poor performance for participating laboratories.
- Data are standardized
- Data are treated as confidential
- Participants are compliant to reporting their results

**Annex:** proposal for reporting results rounds within project setting

**Report on EQAT Rounds 14<sup>th</sup> February 2005 – 31<sup>st</sup> October 2006**

<b>NRC</b>	<b>Date round</b>	<b>Compliance</b>	<b>Summary Results</b>	<b>Comments e.g. aims achieved, procedure etc.</b>	<b>Actions taken</b>
<b>ATB susp</b>	1.				
	2.				
	3.				
	4.				
	5.				
	6.				
	7.				
<b>Salmonella</b>					
<b>Measles</b>					
<b>Rubella</b>					
<b>Polio</b>					



**Annex 8      Side letter No. 9**

**SIDE LETTER No. 9**

**TO TWINNING CONTRACT 2003-004-995-03-07/0001  
“Strengthening the surveillance and control of Communicable Diseases”**

Twinning No. SK/03/IB/SO/01

Both Twinning partners have agreed the following:

**Art. 1 Objective**

1. The objective of this Side letter is to notify reallocations in the “Budget for Action” (annex III) to the Twinning Contract 2003-004-995-03-07-0001.

Overall project budget remains as contracted.

**Art. 2 Modification**

The reallocations are mentioned in the Notification of Reallocations No 6 (annex 1).

The modifications were made for the following reasons:

- On request of the Dutch STE and as part of activity 2.6 the RTA will make a trip to the National Reference Center in Kosice in order to gather information on quality management issues, which then can be used for the evaluation of the quality system in activity 2.7.
- For this reason it is necessary to stay one night in Kosice. The RTA therefore requests a per diem for one day.

The budgetary implications are presented under budget section 2 of the Notification of Reallocations No 6 enclosed with this letter. The estimated costs of mentioned modifications amount to € 160 and will be financed out of activity 2.6 out of savings from Per Diems. Not used savings remain within the original budget line. No other changes have been made in Notification of Reallocation No6.

The reallocations were made for a cumulated amount of less than 10% of the total budget for this Twinning project.

**Art. 3 Confirmation of validity**

All of the parts and dispositions of the initial Twinning Contract 2003-004-995-03-07/0001 and the approved side letters or addenda which are not modified here remain valid.

Read and approved for the parties of the Twinning Project:

Mr. Geert van Etten,  
Project Leader

Ms. Zuzana Škublová  
Project Leader

**Annex:** revised budget

**Annex 9      Report RTA – trip to Košice**

<b>Regional Public Health Authority in Košice</b> <b>NRC for diphtheria</b>  29-30 May 2006		
Visitors:      Ms. Annemarie Aalders, RTA Ms. Jana Ráčková, RTA Assistant  Persons met:   Dr. Irena Miková, Head Section of Medical Microbiology Dr. Lengyelová, Head Department of Virology Dr. Igor Masica, Head Section of HIV/AIDS		
1	Is there a valid Quality manual?	Yes, see also point 3
2	Where are they in the SNAS accreditation process? (I understood they will be accredited together with the biochemical laboratory?)	<p>The 3 NRCs (NRC for Diphtheria, NRC for Listeriosis and NRC for Enteric Parasitology) have been visited by SNAS in March 2006.</p> <p>The <u>NRC for Diphtheria</u> is part of the Phare Twinning project.</p> <p>2 separate reports from SNAS. 1 on the quality manual and 1 on the assessment on the place.</p> <p>The SNAS said that the lab's are ok, only descriptions and documentation was not so good. Some of it has to be written according to the new norm (see also point 4).</p> <p>Other explanation:  There are 2 methodologies for diphtheria: bacteriology and serology.  For bacteriology there is a separate lab with methods and equipment that have to be accredited.  Serology part is closely connected with virology work (both using cell cultures, same staff ... etc.) therefore both are located in the same labs even using the same equipment. The work concerning serology has to be accredited therefore all equipment used for this work is labelled as "accredited". The equipment used only for virology is labelled as "unaccredited" because the virology accreditation is not taking place now, maybe in the future.</p>
3	Are there unsolved non-conformities from SNAS report?	There are around 30 non conformities (2 main, 22 middle, 4 small, 2 very small) for the 3 NRCs.

		<p>Most of them can be and will be solved by 25/5.</p> <p>The non conformities concerning the quality manual will be solved around 2/6.</p>
4	<p>Did they already upgrade the system to the new ISO 17025:2005? (Maybe give the Quality Manager my overview of the differences?)</p>	They are already working with the new norm.
5	Are all necessary SOP's written?	Yes
6	Are the SOP's in the laboratory all valid (signed and dated)?	Yes
7	Are the equipment checklists filled in?	Yes
8	Is the equipment calibrated and does that show on the equipment?	
9	Which proficiency schemes are they involved in?	
10	Can they show some internal audits reports?	
11	Can they show some customer or internal complaints?	
12	Are corrective and preventive actions finished?	
13	Can they show a management review?	
14	Are there still reconstruction issues?	The NRC is situated in a historical building, a monument. Therefore the building has to be reconstructed in the original way. The lab for a.o. diphtheria has been reconstructed already in a modern way.
15	Any other remarks	<p>Overall Impression:</p> <ul style="list-style-type: none"> <li>▪ Very clean and well organized NRC.</li> <li>▪ In all rooms there were lists with descriptions, SOP's, on the wall; notebooks with date were up to date.</li> <li>▪ No personnel around (visit took place between 14.30 and 16.30).</li> <li>▪ Unclear is how much work there is during working hours. Dr. Miková explained that they have highly specialized work and some days are busier than other days. Not much routine daily work.</li> <li>▪ Only 16 employees of which 9 are working part-time in NRCs as well as working in virology (ad-</li> </ul>

		<p>vantage of sharing knowledge).</p> <p>Negative points (not through fault of Dr. Miková):</p> <ul style="list-style-type: none"> <li>▪ New computer available but no relevant laboratory software. Consequence is that they still do everything by hand, writing data in notebooks.</li> <li>▪ No active quality manager. Only existing in the organizational structure.</li> </ul>
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**Annex 10      Report Mr. Melchers – activity 2.6**

## **Twinning Project**

Twinning No. SK03/IB/SO/01

### **Strengthening the Surveillance and Control of Communicable Diseases**

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## **MISSION REPORT**

**EXPERT NAME: Dr Willem JG Melchers**

**COMPONENT: 2**

**ACTIVITY NO.: 2.6**

**DATES OF VISIT: June 12 – 15, 2006**

#### **Activities according to the Work Plan**

- Evaluation of the progress of RAPD for genetic analysis of Salmonella by NCR
- Evaluation of the possibilities to implement real-time PCR for the detection of enterovirus, parvovirus en meningococci genotypes
- Analyse the situation for the molecular unit and the potential to implement new, advanced molecular detection techniques.

#### **Summary discussed items (bullets)**

- Briefing with component coordinator and RTA
- Discussions in detail with Staff members
- Discussion progress RAPD method for molecular fingerprinting of Salmonella serotypes
- Discussion real-time PCR methods for molecular genotyping of meningococci
- Debriefing with component coordinator and RTA

#### **Persons met Name**

#### **Position**

Dr. Jana Bošá	Head of NRC Medical Microbiology
Dr. Dagmar Gavačová	Head of NRC Salmonellosis
Dr. Jana Černická	Biologist of NRC Molecular diagnostics
Annemarie Aalders	RTA
Jana Ráčková	RTA assistant
Dr. Kamil Boleček	General Director SVFI

#### **Conclusions (bullets)**

- The progress in implementation of RAPD for the genetic analysis of different Salmonella serovars is impressive. The expert feels an important step forward would be to

gain more knowledge about the interpretation of the massive amount of data.

- For further interpretation, it will be important to incorporate PFGE as a confirmatory and additional genotyping method.
- There seems to be controversy against the implementation of real-time PCR technology versus conventional PCR methods, especially for enterovirus. This is mainly based on differentiated responsibilities that could influence future developments.
- The set-up of the molecular unit is in progress but delayed because the reconstruction of the labs is expected to start next month, the actual new set-up could therefore practically not be evaluated. In theory it looks fine.

#### Recommendations (bullets)

- As stated also in the previous Mission report, the NCR is now establishing the infrastructure for reliable molecular diagnosis. This point will influence all further developments in this area and I therefore consider this aspect as a major break-point for future work. At this point I still highly recommend to bring all molecular diagnostics work in a single unit under the supervision of full-area over-viewing head. This means that both molecular diagnosis and typing should be concentrated in the separate laboratories (clean-lab, clinical lab and analysing lab). In the analysis lab all available and new equipment (PCR, LightCycler, PFGE) should be brought together, accessible for every assay.
- I would recommend Dr. J. Černická to be the Head of this new molecular unit, with full responsibility and power to implement these new technologies.
- It is recommended that Dr. J. Černická will get extensive training possibilities in this area. Especially an internship in an established laboratory is recommended. By doing so, she can learn all potentials and pitfalls of these technologies in a relative short time period without being confronted with these issues in her own setting from the start.
- It is recommended to implement RAPD and PFGE as molecular tools for outbreak and epidemiological analysis in the laboratory setting in a broad perspective.
- It is recommended to incorporate the molecular diagnosis of parvovirus by PCR and enterovirus and meningococci genotypes by real-time PCR (LightCycler)
- As indicated previously, it will be important to establish a Slovakian working group on molecular diagnosis in which open discussions concerning newly acquired experiences will extend the possibilities to introduce these techniques country-wide.
- It will be important to establish a net-work for proficiency-panels to quarantine quality assessments, the NCR can be leading in this issue.

#### Follow-up by RTA (bullets)

#### Remarks (bullets)

- I was impressed by the large amount of work on RAPD for Samonella Dr. Jana Černická has accomplished since my last visit.
- As the number of activities planned in the mission could be addressed in a relative short period of time, the expert's presence was ineffectively used. This was partly due to the coming elections and the related problems, but I feel it would have been much better if the mission was either delayed or cancelled.

- Because of this “spare” time, I have visited the State Veterinary and Food Institute, especially related to the molecular biological activities. Although the visit was interesting and informative, it was actually not a part of the mission’s activities.

<b>Evaluation (bullets)</b>	
<b>Positive</b>	<b>Negative</b>
1 Impressive amount of work done 2 Dr. J. Černická is a very good potential internal candidate as head of the molecular unit	1 The limited content of the mission 2 Mission was not well planned

Date/signature of Expert	Date/signature of Component co-ordinator	Date/signature of Adviser
Bratislava, June 15, 2006	Bratislava, June 15, 2006	Bratislava, June 15, 2006

**Annex 11 Report Mr. Galama – activity 2.6**

## **Twinning Project**

Twinning No. SK03/IB/SO/01

### **Strengthening the Surveillance and Control of Communicable Diseases**

## **MISSION REPORT**

**EXPERT NAME Dr Prof. dr. J.M.D. Galama**

**COMPONENT 2:** Development and implementation of the quality control systems and progressive detection methods.

**ACTIVITY NO. 2.6**

**DATES OF VISIT 10/07-12/07/2006**

#### **Activities according to the Work Plan**

- ☐ Activity according to workplan:
  - Development and implementation of the quality control systems and progressive detection methods.
- ☐ Specific description from component co-ordinator:
  - Maintaining of a high level of expertise and performance of diagnostics of Measles, Rubella, Poliomyelitis and Influenza in the Regional Public Health Authorities in Banská Bystrica and Košice.
  - An evaluation of fulfilment of the standard operating procedures at regional level.

#### **Summary discussed items (bullets)**

<b>Persons met Name</b>	<b>Position</b>
Dr. Jana Bošá	Coordinator component 2
Dr. Jarka Tiezová	Head TC and MMR laboratory
Dr. Renáta Kissová	Head Virology Department PHA, BB.
Dr. Sonja Feiková	Department of Molecular Biology
Dr. Desana Kohutová	Head of the Serology Department
Dr. Majlathová	Quality manager
Dr. I. Miková	Head Microbiology department PHA, K.
Dr. V. Lengyelová	Head Virology Department PHA, K.
Mrs Annemarie Aaldersová	RTA
Mrs Jana Ráčková	RTA assistant

#### **Conclusions (bullets)**

**Both labs (BB visited on July 10<sup>th</sup> and Kosice, July 11<sup>th</sup>)**

- Technically the laboratory system is on a satisfactory level. The virus-isolation system may in future be further improved by introduction of virus isolation procedures on 24-wells

plates, enabling to increase sensitivity of virus isolation by a centrifugation step (the improvement is not essential).

- Detection can be speeded up with monoclonal antibodies (the improvement is not essential for public health issues but may be, it is for diagnostics).
- The labs have now a quality system operational, which will be evaluated separately by Mrs de Schipper.
- Administration is still hand-written in booklets, thus a software system is eagerly welcomed.
- Few clinical and surveillance samples are received by the labs. Including sentinel samples < 300 for enteroviruses and the numbers drop yearly. The number of samples for respiratory viruses remained stable but also at low numbers.
- The numbers of samples for serology is also limited (Since January, the lab in Kosice received only 20-30 samples for respiratory viruses).
- It was discussed that hospital labs which in part are privatized, increasingly take over diagnostic activities. However, their contribution to a national surveillance system is limited because these labs do virology testing mainly through serology, which is inadequate for acute infections.
- PCR is implemented for anthrax and some respiratory pathogens only. There is limited budget for further extension of its application.
- Gastro-intestinal infections are screened for the most common viruses (Rota and adenovirus) but not for Noroviruses which are important from a PH point of view.
- Polio antibody screening is done at the central lab in Bratislava.
- There is limited opportunity for the professionals to keep up with recent developments and standards through post-graduate trainings.
- There is quite a distance between the lab and the clinic which makes that virology has currently a weak position in clinical decision making.

#### **Recommendations (bullets)**

The role of clinical virology should be strengthened because of its great importance for public health as well as its rapidly growing clinical relevance. From discussions in both labs and with the Component Coordinator in Bratislava a general recommendation is to bring virology nearer to the patients and their doctors: This can be achieved as follows:

1. Increase attention for clinical virology in the medical curriculum at Universities (Virology, not only within the Science Faculty but also in the Medical Faculty).
2. Integrate virology in the clinical diagnostic process by introduction of viral diagnostic units in the Microbiology Departments of University Hospitals and large Teaching Hospitals.
3. Providing training of medical professionals how to apply viral diagnostics.
4. Increase number of clinically relevant diagnoses, which will improve sight on the prevalence and incidence of viral infections.

The role of the Public Health Authority (PHA SR) may eventually change towards a more general position as National Reference and Surveillance Centre in which all smaller centres may be included and concentrated. The centre may work in close collaboration with expert centre from Universities on Public Health issues such as epidemiological typing of isolates gastrointestinal viruses and provide the local labs with qualified reagents for the diagnostic work etc. By means of contracts the more or less independent hospital laboratories may become more tightly involved in Public Health.

A separate recommendation is to organize post-graduate training and accreditation of professionals in the 3 Public Health Laboratories, which should, as far as not already achieved, become integral part of the quality system.

**Follow-up by RTA (bullets)**

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**Remarks (bullets)**

--

**Evaluation (bullets)**

Positive		Negative	
1		1	
2		2	
3		3	

Date/signature of Expert	Date/signature of Component co-ordinator	Date/signature of Adviser

**Annex 12     Side letter No. 8**

**SIDE LETTER No. 8**

**TO TWINNING CONTRACT 2003-004-995-03-07/0001  
“Strengthening the surveillance and control of Communicable  
Diseases”**

Twinning No. SK/03/IB/SO/01

Both Twinning partners have agreed the following:

**Art. 1 Objective**

The objective of this Side letter is to appoint Mrs Catharina de Schipper-Visser as expert for activities 3.3 and 3.4 (article 4. Tasks of Annex I), replacing Mrs Wendy Waijboer who is no longer able to work as expert for the project because she has taken up a new job in the Netherlands as from the first of April 2006. The proposed expert has the same qualifications and field of expertise, being specialised in Quality Control Systems in relation to surveillance and public health (annex 1 – CV of Mrs. de Schipper-Visser).

**Art. 2 Modification**

In Art. 5 (Human Resources) and Art. 6 – Work schedule.  
The expert Waijboer for activities 3.3 and 3.4 is replaced by expert de Schipper-Visser; the fee will remain 335 euro for each working day. The replacement of Mrs Waijboer by Mrs de Schipper-Visser has no implications for the budget.

**Art. 3 Confirmation of validity**

All of the parts and dispositions of the initial Twinning Contract 2003-004-995-03-07/0001 and the approved side letters or addenda which are not modified here remain valid.

Read and approved for the parties of the Twinning Project:

For Mr. Geert van Etten, Project Leader  
Annemarie Aalders, RTA

Ms. Zuzana Škublová  
Project Leader

**Annex 1: CV Mrs de Schipper-Visser**

**CURRICULUM VITAE**

Proposed role in the project: **Expert on Quality assurance for laboratories**

1. Family name: de Schipper-Visser
2. First names: Catharina Jeannette Wilhelmina (Karin)
3. Date of birth: 19 april 1962
4. Nationality: Dutch
5. Civil status: Married, 3 children
6. Education:

<b>Institution</b>	<b>Date: from (m/y) to (m/y)</b>	<b>Degree(s) or Diploma(s) obtained</b>
Utrecht School of Governance, Utrecht University	Jan/2003 - Dec/2004	MA in Public Administration (Organisation, Culture and Management)
Maruna, Leiden	1/2001 - 2/2001	Certificate Applied Laboratory Statistics
Academy for Higher Professional Education, West Brabant	3/1999	Certificate Integral Quality Care for Medical Laboratories
Kerteza and Co-ordination Committee for Quality in Medical Laboratories (CCKL), Belgium	2/1999	Certificate Internal Auditor for Medical Laboratories
Department of Community, occupational & family medicine, National University of Singapore, Faculty of medicine.	10/1996 - 11/1996	Certificates Health Education and Health Promotion
Van den Broek Institute, Amsterdam	8/1983 – 6/1985	Certificate Laboratory Technology: Immunology
Van 't Hoff Institute, Rotterdam	8/1978 – 8/1981	Bsc Laboratory Technology: Clinical Chemistry

7. Language skills (5=excellent, 4=good, 3=satisfactory, 2=fair, 1=weak for competence)

<b>Language</b>	<b>Reading</b>	<b>Speaking</b>	<b>Writing</b>
-----------------	----------------	-----------------	----------------

Dutch	Native		
English	5	5	5
German	5	3	2
Indonesian	5	5	5

8. Membership of professional bodies: -

9. Other skills; (e.g. Computer literacy, etc):

Project management; computer skills (Office, database and laboratory applications); financial and secretarial skills; tropical medicine, leprosy.

10. Present position:

Company/location	Position	Description
A) Leiden University Medical Center (LUMC)	<ol style="list-style-type: none"> <li>1. Quality Co-ordinator for the Central Laboratory for Hematology (CKHL)</li> <li>2. Quality Co-ordinator for one of the five divisions of the LUMC (started 2/2004).</li> <li>3. Advisor</li> </ol>	<p>1. Co-ordination and management of quality system of the Central Laboratory for Hematology; communication with the bodies that grant accreditation; management of and participating in, projects for quality improvement; training of students in the area of Quality Care.</p> <p>2. Co-ordination of the quality activities within the division; the coaching of other Quality co-ordinators within the division. Linking pin for interdivisional and central quality activities within the LUMC as a representative of the division.</p> <p>3. Advise and management of projects for improvement of the quality of public service.</p>
B) Netherlands School of Public and Occupational Health (NSPOH)	Technical advisor	Advises on co-ordination and management of quality systems within International Projects

11. Years within the firm:

A) 8 years

B) 0,5 year

## 12. Key qualifications (relevant to the project):

- A broad expertise in developing, maintenance and evaluation of Quality Systems specific according to ISO 17025 and ISO 15189.
- A broad expertise in the development, maintenance and evaluation of Standard Operating Procedures.
- A broad expertise in internal auditing
- Expertise in interpreting and evaluating Quality Control schemes.
- A broad experience in training, advising and coaching, also with intercultural teams in an international setting and in projects

## 13. Specific experience abroad:

<b>Country</b>	<b>Date: from (m/y) to (m/y)</b>	<b>description</b>
Indonesia	6/1988 – 5/1997	Staffmember The Leprosy Mission International (TLMI) as a counterpart to employees of the Health Service of the Indonesian Government in the provinces “Irian Jaya” and “Nusa Tenggara Timor”. Including e.g. Formal and on-the-job training; health promotion and -education activities; monitoring and evaluation of medication compliance of patients; preparing and evaluating project agreements; financial- and office-management; collecting and preparing epidemiological data for evaluation.

## 14. Other professional experience record:

<b>Date</b>	<b>Company/location</b>	<b>Position and description</b>
1998-2003	Leiden University Medical Center (LUMC); Central Laboratory for Hematology (CKHL).	Laboratory technician Preparing and examining blood- and bonemarrow slides for diagnoses and follow-up of hematological malignities. Training of (medical) students and medical doctors in this area of expertise.  First year full-time and from 1999 onwards in combination with coordinating and managing the Quality system as described earlier.

Date	Company/location	Position and description
1982-1987	Free University Medical Center, Amsterdam; Hematological Laboratory.	Laboratory technician Bloodbank and Special Hematology including examining blood- and bonemarrow slides for diagnoses and follow-up of hematological malignities and evaluating coagulation problems. Developing new techniques for coagulation tests and bonemarrow culture. Training of (medical) students, new colleagues and medical doctors in this area of expertise.

## 15. Other:

Member of Personnel Committee TLMI

Publications:

## 16. Contact Address in the Member State, including telephone, fax and e-mail

Karbonkelstraat 8,  
2403 BV Alphen aan den Rijn,  
Phone: +31172415195,  
Mobile phone: +31648210703,  
E-mail: deschipper@planet.nl

## Annex 13 Time schedule

2005													2006									
Calendar Month	from/to	14/2 13/3	14/3 13/4	14/4 13/5	14/5 13/6	14/6 13/7	14/7 13/8	14/8 13/9	14/9 13/10	14/10 13/11	14/11 13/12	14/12 13/1	14/1 13/2	14/2 13/3	14/3 13/4	14/4 13/5	14/5 13/6	14/6 13/7	14/7 13/8	14/8 13/9	14/9 13/10	14/10 31/10
Project Month		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Phase	0	Phase 1				Phase 2							Phase 3									
Inception period / "Kick-off"	RTA																					
Component 1																						
Activity 1.1		RTA																				
Activity 1.2		x																				
Activity 1.3			Otto (3 days)																			
Activity 1.4			Holvast (4 days)																			
Activity 1.5			van Pelt (5 days)																			
Activity 1.6			Otto (3 days)																			
Activity 1.7			Otto (5 days)																			
Activity 1.8			Otto (5 days)																			
Activity 1.9			Otto (5 days)																			
Activity 1.10			LCI (Timen) (2 days)																			
Activity 1.11			LCI (Timen 2 days) + (van Stiphout 2 days)																			
Activity 1.12			RTA + extension: workshop																			
Activity 1.13			Otto (2 x 5 days)																			
Activity 1.14			RTA																			
Activity 1.15			RTA+ extension: training																			
Component 2																						
Activity 2.1		RTA																				
Activity 2.2			Mulder, Galama, Waijboer (3, 4, 7 days)																			
Activity 2.3			RTA																			
Activity 2.4			Waijboer (3 days)																			
Activity 2.5			Melchers, Galama, de Schipper (2, 2, 3 days)																			
Activity 2.6			Melchers, Galama, de Schipper (3, 3, 4 days)																			
Activity 2.7			de Schipper (5 days)																			
Activity 2.8			RTA																			
Component 3																						
Activity 3.1		RTA																				
Activity 3.2			Waijboer (3 days)																			
Activity 3.3			de Schipper (1 day)																			
Activity 3.4			de Schipper (7 days)																			

**Annex 14 Overview activities until end of project**

(version 2/8/2006)

<b>Activities</b>	<b>Date</b>	<b>Experts</b>	<b>Remarks</b>
<b>activity 1.10: Extension:</b> Formulation of Slovak specific general guidelines with the help of Dutch guidelines: Extra proposal	Deadline: Sept.	Slovak Translation Office	
<b>activity 1.12</b> Registration for new memberships of EU networks	Deadline: Sept.	RTA, PM and CC Comp. I	Corresponds with act. 1.5
<b>activity 1.12: Extension:</b> 1 day workshop into the use of ENTERNET network: Extra proposal	5/9	Wilfrid van Pelt, Arjen van der Giessen	
<b>activity 1.13</b> Implementation, testing and evaluation of the new systems on data collection in 5 selected pilot regions	21-25/8: 2 <sup>nd</sup> part	Matthias Otto	1 <sup>st</sup> part of this activity took place from 10-14/7
<b>activity 1.14</b> Full systems roll-out in all 36 Regional PHA's	At the same time as act. 1.13	RTA	RTA will support the company responsible for the TA in the implementation of the new system in all 36 workplaces
<b>activity 1.15</b> - Organization of a one day conference on Intervention epidemiology for surveillance and control of communicable diseases at the national and local level (integrated in extension act. 1.15, see below) <b>Extension:</b> - 4 day training on epidemiological principles in general and on risk assessment: Extra proposal Total: 5 days: 1 day preparation, 3 days training advanced epidemiological principles (Case control and Risk assessment), 1 day conference (original act. 1.15)	18-22/9	RTA Hannelore Gotz Jeanette de Boer	Advanced training on epidemiological principles  Combined with act. 1.11
<b>activity 2.7</b> Final assessment of the implementation of the new quality control system	4/9-8/9	Karen de Schipper	
<b>Activity 2.8</b> Passing the accreditation process	Before end of project??	RTA	The process is running. RTA is keeping track of it
<b>activity 3.4</b> Implementation and testing in 5 selected pilot workplaces of Standard Operating Procedures for external quality assurance	4/9-8/9	Karen de Schipper	Will be combined with act. 2.7, 2/3 days

**Annex 15      Financial report No. 6**