MANUAL FOR COORDINATORS
AND DATA COLLECTORS

Training module for data collectors
(Time Location Sampling)

February 2012
This manual is written for persons who have been hired to perform or to supervise data collection in the SIALON II project, a bio-behavioural survey which collects behavioural and biological data among men who have sex with men (MSM) in different European countries. The manual is divided into different sections: The first section of the guidance discusses the rationale and objectives of SIALON II. Understanding the rationale and objectives is important because it may help you justify participation to potential respondents and thus motivate persons to join the study or to provide valid and complete information. The second section defines the role of the coordinator and data collectors within the framework of the research. The third and fourth sections focus on field data collection procedures and prevention activities, and the training of data collectors by the coordinator and provide detailed instructions on how to administer the questionnaire and collect the oral fluid samples.
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## 0. Abbreviations and definitions

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<th>Abbreviation</th>
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<tr>
<td><strong>DGSANCO</strong></td>
<td>Directorate General for Health and Consumers (of the European Commission)</td>
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<tr>
<td><strong>Downer</strong></td>
<td>Drugs taken to relax or to feel less pain/irritations during sexual activities</td>
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<td><strong>ECDC</strong></td>
<td>European Centre for Disease Prevention and Control</td>
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<td><strong>EFTA</strong></td>
<td>European Free Trade Association</td>
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<td><strong>EU</strong></td>
<td>European Union</td>
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<tr>
<td><strong>FAQ</strong></td>
<td>Frequently Asked Question</td>
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<td><strong>GBL</strong></td>
<td>Gamma ButyroLactone. Drug, usually taken to relax and be more sexually aroused. Also sold as a strong cleansing product. The human body transforms GBL into GHB</td>
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<td><strong>GHB</strong></td>
<td>Gamma-HydroxyButyrate. Less concentrated than GBL, with lesser effect</td>
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<tr>
<td><strong>Hallucination</strong></td>
<td>A sense perception (sight, touch, sound, smell, or taste) that has no basis in external stimulation</td>
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<td><strong>HCV</strong></td>
<td>Hepatitis C</td>
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<td><strong>HIV</strong></td>
<td>Human Immunodeficiency Virus</td>
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<td><strong>MDMA</strong></td>
<td>The activating substance in Ecstasy, drug with hallucinating effects, also a an upper (activating effect)</td>
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<td><strong>MSM</strong></td>
<td>Men who have Sex with Men</td>
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<td><strong>NGO</strong></td>
<td>Non-Governmental Organization</td>
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<tr>
<td><strong>PEP</strong></td>
<td>Post Exposure Prophylaxis</td>
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<td><strong>PrEP</strong></td>
<td>Pre Exposure Prophylaxis</td>
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<td><strong>RSP</strong></td>
<td>Regular sex partner: A partner you regularly meet for sexual encounters</td>
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<tr>
<td><strong>SGSS</strong></td>
<td>Second Generation HIV Surveillance System</td>
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<tr>
<td><strong>SSP</strong></td>
<td>Steady (sex) partner, the partner you have a relationship with</td>
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<td><strong>CSP</strong></td>
<td>Casual sex partner, one night stand</td>
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<td>Abbreviation</td>
<td>Definition</td>
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<td>RDS</td>
<td>Respondent-Driven Sampling: The sampling method that relies on social network properties to sample hard-to-reach populations</td>
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<td>RUOI</td>
<td>Receptive unprotected oral intercourse with ejaculation</td>
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<td>STI</td>
<td>Sexually transmitted infection</td>
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<tr>
<td>TLS</td>
<td>Time-location sampling: A sampling method that recruits individuals from specific locations during specific time periods</td>
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<tr>
<td>UAI</td>
<td>Unprotected anal intercourse</td>
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<tr>
<td>Upper</td>
<td>Popular term for any amphetamine or neurostimulant. Drugs taken to enable longer lasting and more intense experiences, e.g. dance all night</td>
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<td>Venue</td>
<td>Locations where the target population, in our case MSM, congregates</td>
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<td>VDT</td>
<td>Venue-day-time periods: Manageable 4-hour units of time that are venue, day, and time specific. VDTs are identified through a-priori staff knowledge, community interviews, owners and type I (if necessary) enumerations</td>
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<tr>
<td>XTC</td>
<td>Abbreviation of Ecstasy, drug with hallucinating effects, also an upper (activating effect)</td>
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<tr>
<td>Sero discordant couple</td>
<td>Couple existing of one HIV positive and one HIV negative partner</td>
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1. Research rationale and objectives

Rationale

HIV infection remains an important public health issue in Europe. In the European Union (EU) and European Free Trade Association (EFTA) countries the predominant mode of transmission is sexual contact among men who have sex with men (MSM) (40%), followed by heterosexual contact (29%). The number of HIV cases among MSM has increased by 19% between 2004 and 2008 and this group continues to represent a population at high risk of HIV infection. Furthermore, there is accumulating evidence that the number of newly diagnosed HIV cases among MSM has been increasing in recent years, including recently acquired and acute infection.

In order to improve the quality of information and the effectiveness of preventive actions, WHO and UNAIDS have developed the Second Generation HIV Surveillance System (SGSS). The main objective of SGSS is to monitor HIV and high-risk behaviour trends over time in order to provide essential data needed for the development of interventions and the evaluation of their impact. Former EU funded SIALON I project (Capacity Building in HIV/Syphilis Prevalence Estimation using Non-Invasive Methods among MSM in Southern and Eastern Europe) helped to implement a methodological framework in line with Second SGSS. In particular, SIALON I developed a client friendly method of gathering biological, behavioural and contextual data among MSM. Data collected in SIALON I could be used by policy and decisions makers to design policies and strategies for building comprehensive approaches to addressing the immediate and long term prevention treatment and care services for MSM, as well as by gay organisations and other civil society networks. The current project - SIALON II project (Capacity building in combining targeted prevention with meaningful HIV surveillance among MSM) - has been approved for funding under the 2008-2013 Public Health Programme. The overall objective of the SIALON II project is to carry out and promote

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combined and targeted prevention complemented by a meaningful surveillance among MSM. In other words, the aim of this project is to develop capacity building and knowledge through both training and on-site coaching under the active supervision, and in collaboration with, UNAIDS and WHO on: a) prevention needs assessment and prevention actions, and; b) innovative surveillance methodologies for hard to reach populations like MSM.

**Objectives**

In particular, the present project has the following objectives:

- the implementation of a bio-behavioural survey using different sampling methods, namely Time-Location Sampling (TLS) in Belgium, Bulgaria, Germany, Poland, Portugal, Spain, Sweden, Slovenia and UK, and Respondent-Driven Sampling (RDS) in Italy, Lithuania, Romania, Slovakia, Armenia and Moldova.

- To estimate prevalence of anti-HIV Ab based on testing of saliva samples among MSM in the data collection sites though TLS method.

- To estimate HIV, T. pallidum, HBV, HVC infection based on testing of serum samples among MSM in the data collection sites through RDS method

- To identify, describe and analyse sexual risk behavioural patterns, and sexual health in the MSM population through a survey modelling the relationship between risk behaviour, socio-ecological or contextual factors and biological samples

- To pilot the algorithm for the following testing procedure, both in terms of technical procedures and in terms of acceptability from the point of view of the target population: rapid test for HIV-Syphilis in MSM population in the context of a surveillance system.

- To organize prevention activities in the context of TLS
2. Actors: coordinator and data collectors

Actors involved in TLS data collection are the coordinator and data collectors.

The **coordinator** is selected and hired by the associated partners at country-level: his/her job is to co-ordinate the complex process of data collection; ensuring harmony between the data collection process; and the broader prevention activities; to process questionnaires and biological samples eventually; to organize and perform data input. The coordinator therefore has a fundamental role, coordinating the work of data collectors in the field following recommendations of associative and collaborative partners, and using official project material.

**Data collectors** are the people who collect the data in the field, and are therefore responsible for approaching respondents, for administering the questionnaire, for collecting oral fluid and for implementing prevention activities. They are chosen at country level by local partner’s coordinator using the effectiveness criteria stipulated in the part of the handbook dedicated to co-ordination [*section 3*]. Data collectors work under the co-ordination and supervision of the coordinator.

A flow chart table of data collection’s procedures is at the end of this manual [*table 1*].

3. Coordination actions

3.1. Analysis of pre-conditions

Since the sampling frame will be provided in detail just before the start of data collection, in terms of locations and scheduling, it is important to bear in mind all the features that guarantee feasibility and safety, in each location, and this involves assessing settings such as outdoor cruising and commercial settings (bars, discos, saunas, etc.). Ensuring ethical and safe environmental conditions for data collection is the responsibility of the coordinator, who should give out all the required information
and take all the necessary actions to guarantee proper working conditions for data collectors.

In general, the following conditions should be guaranteed for data collection and sampling:

- Safety of and lack of physical risk for data collectors (see section 4.2)
- Clarity and non-ambiguity of the role of data collectors in the specific setting
- Logistic feasibility for data collection
- Privacy for respondents

These guarantees differ for the various settings. The most evident distinction to be made is between outdoor cruising and commercial settings (bars, discos, saunas, etc.).

- **Outdoor cruising: logistics feasibility and safety**

Cruising settings (parks, beaches, etc.) involve **usually outdoor locations which are hard to control** by data collectors and in general anyone else: it is impossible to control who is coming and going, and often areas are hidden from view (particularly at night). This increases the degree of risk. Hence it is important to make sure there is a safe exit route in the event of critical situations and establish procedures beforehand, as specified sections 4.1 and 4.2 of this handbook: the method of approach and working method, as well as the positioning of data collectors in the setting, should be such as to ensure that the situation does not slip out of control. Data collectors must always be in pairs, or, better still, two pairs for all outdoor cruising settings.

Cruising settings also involve **logistics problems**, particularly if they are areas frequented at night or on foot: is the lighting good enough to fill in a questionnaire? The respondent has to stand or can he sit down (in view of the fact that it takes 10 minutes to fill in the questionnaire)? These and other aspects of the
location need to be investigated and proper logistics solutions found. The hard clipboard used for the questionnaire is a help, for example, in many situations.

- **Commercial locations: agreements with owners and privacy**

Sampling in commercial locations involves arranging set times so in this case **an agreement with the owner is required**, so he/she should be contacted. When meeting with venue owners, the coordinator should emphasize individual and community benefits of the study to the community, and that sampling activities will be conducted in ways to minimize burden on venue management and patrons. In particular, various aspects should be agreed upon to prevent misunderstandings later which might involve data collectors in having to renegotiate their presence each time.

These include:

- an exact timetable;
- how customers are to be approached (where, what they are asked to do, etc.);
- positioning in the location and logistics (at the entrance, casually inside, at a dedicated table, etc.);

In crowded locations or when the respondent is surrounded by others, a private area should be found for the respondent to fill in the questionnaire, in agreement with the owner/manager. Moreover, a compromise needs to be found between being in a position which enables the approach to respondents and not creating confusion and misconceptions about the role of the data collectors.

3.2. **Liaising and agreement with labs**

Liaising and agreement of associated partner with the laboratories should be made in order to test gathered saliva samples approximately in one week after the collection.
In the case samples will be found HIV-reactive in the 1st testing lab will provide 2nd anti-HIV Ab testing either from saliva or from the blood.

3.3. Recruitment of data collectors

Data collectors are recruited and trained with the involvement of gay or prevention associations (NGO’s) in each participating country. If possible, data collectors should be recruited among people belonging to the target group: this criterion greatly increases both the compliance to the study and the validity of the data collected. According to local context and customs, it is also possible to recruit people who don’t belong directly to the target group, but only if they are strongly perceived and recognized as “friendly” to them. In any case it is recommended always to include some collectors who belong to the target group as focal points of the process during data collection in the different settings.

Data collectors must be:

- good communicators, able to explain the scope and aim of the research, in particular if respondents request further information;
- inspire trust, able to persuade and motivate respondents, overcoming any diffidence;
- reliable, able to carry out their functions as specified;
- able to manage any critical situations that might arise, both in terms of their own safety and the behaviour of respondents;
- blend into the various settings, look and feel comfortable where data is collected.

Ideas to specify the profile of the data-collector; the specifications can be used as a checklist for already present qualities and qualities to pick up by potential data-collectors during intake:
**Knowledge**

- Knowledge of the transmission of HIV and STI’s.
- The physical, mental and social aspects and the effects of alcohol and (other) drugs and the relation of these aspects on risk increasing sex concerning HIV and STI transmission.
- Knowledge of the local MSM scene. Know where to find what activities, type of visitors and knowing how to get there.
- Familiar with the local health and wellbeing services.

**Skills**

- Create an atmosphere without prejudices where the responded feels save and respected services.
- Create a professional atmosphere where there are no taboos in speaking about sexuality.
- Knowledge of the local gay health map in case respondents needs to be referred.
- Good communication skills: Communication with all kinds of people will occur. For example, different kind of staff member and visitors of different SES, rural or city background, all kind of personalities, different gay subcultures.
- Creative in finding solutions when things don’t happen as planned.

**Attitude**

- Respectful: no judgments of lifestyle of clients.
- Open minded: being able to work in completely different gay venues, from a cozy atmosphere to venues where explicit sexual actions can be seen.
- Flexible: Irregular hours should not be a problem, as well as adapt to the local situation.
- Firm where needed: being able to communicate with clients which have used alcohol or other drugs. Decide if somebody can participate or not.
- Discreet: Information given by and seen from visitors and staff concerning lifestyle and sexual behavior will not be shared with people outside the project team.
• Team player: being able to working in a team, the ability to back up your colleague and having trust in each other is a must.

To bear in mind: During the introduction, the data collector should show respect, interest and appreciation for their respondent’s participation. Previous experiences have shown that this attitude will increase participation rates.

In order to maximize the staff diversity (cultural and skill based) and flexibility of operations, having several data collectors is helpful. The number of staff at each sampling event should be proportionately allocated. For example, if a venue has a low flow of participants, it is not necessary to have 4 interviewers present. Nevertheless, data collectors must always be in pairs (logistic and safety reasons).

3.4. Training of data collectors

One month before data collection, coordinators will be trained by the WP5, WP6 and WP8 leaders in a training session during the general meeting in Berlin. Then, a training session should be provided by the coordinator to data collectors in their countries following the instructions detailed in section 4 of this handbook. Training should be provided a few days before data collection in order to be sure that trainees can remember the procedure.

The training session will be developed according to the SIALON I experience and will include a summary of the data collection and prevention manuals:

1. Information on HIV and STI prevention, testing and counselling.
2. Strategies for giving prevention messages and information of gay health services in approaching men in venue settings.
3. Data collection process:
   - Respect the planned time, setting and positioning
   - Safety rules
   - Getting tools ready before approaching
- Approach and invite
- Data collection
- Collection, transportation and storage of oral fluid samples
- Delivery of oral fluid samples and questionnaires to coordinator.

3.5. Monitoring of data collection

Coordinators will be in charge of supervising the local data collection and of coaching data collectors during the task. This is part of the ongoing evaluation process, which could also include regular meetings with data collectors. Coordinators may contact the Veneto Team at any time, by mail, telephone or videoconference (Skype), to receive clarifications about procedures or to agree how to solve difficulties which might arise during the data collection process (including clarifications about questions in the questionnaire).

3.6. Storage and delivery of oral fluid samples to the laboratories

Storage and delivery of samples to the laboratory in each country should be done in the bag or fridge box, depending on environmental temperature as soon as possible. Whole process is deeply described in section 4.8 and 4.9.

3.7. Data input

Each country is responsible for data input for 400 questionnaires. For this purpose an electronic form will be sent to the associated partners by the WP9 coordinator. After inputting data, the database will be sent to the main partner (or uploaded on the web tool).

3.8. Mailing of questionnaires
All questionnaires are also sent to Sweden by post together with the record form and the refusal form: this enables to randomly select a number of questionnaires whose data is re-input in order to evaluate the quality of data entry, according to the protocol.

4. Data collection

4.1. Respect the planned time, setting and positioning

Data collectors must comply with what is established by/with the coordinator in terms of setting, time and positioning [section 3.1].

Scheduling and locations are established and planned by the sampling process and must be complied with: the data collector will have a precise schedule of places and times for data collection provided by the WP5 leaders.

Scheduling alternate VDTs (see sampling manual for details):

Alternative venues will be scheduled and data collectors can go to alternative VDT when:

- Primary venue is inaccessible for unforeseeable reasons or
- there is a temporary lack of safety that could threaten data collectors or
- data collectors don't get enough to fulfil the sample size in primary venue they can go to an alternative VDT until they have reached the sample size

Cancelling VDTs:

If a sampling event must be cancelled prior to their occurrence for some unforeseen reasons such as illness of data collectors, data collector preserves the selected VDT by rescheduling the event for the same day on another week. If the same day is not available in the month, then coordinator should contact the WP5 leader and the VDT will be rescheduled or replaced by some one that has not
been chosen for the month or by a special event (alternate venues are not used to replace cancelled sampling events).

**Positioning** is the concrete spatial positioning in the setting, including the logistics situation: when data collectors take their places in the setting, everything should already have been planned and agreed with the coordinator and, in the event of shopping venues, with the owners.

**List of demands interview area**

- Enough light to write
- Not too much light to give an idea of privacy (which influences the honesty of answering).
- Sound isolation towards a level where a conversation in normal voice is possible.
- Possibility to separate the respondent from other visitors.

**4.2. Safety rules**

It is important for data collectors to avoid trouble though common sense and advance planning, in order to collect data maintaining their personal safety, particularly when settings are cruising areas.

**Work in pairs.** It is recommended to work at all times in pairs, i.e. two data collectors should go to each setting. This is for reasons of safety, above all, but also for situations requiring “problem solving” where two data collectors can immediately discuss a problem.

**Plan ahead.** Each setting should have an emergency plan. Data collectors should know what they are going to do ahead of time in case things suddenly go very wrong. They should know who to contact in case of emergency and where the exits are from each site, including how easily they can be reached. It might be advantageous to have a code word to indicate that a co-worker needs assistance, a “coded phrase” that can be
understood only by them, particularly if the two data collectors go to different respondents at the same time: for example, a data collector who is uncomfortable during the collection with an uncooperative or pushy participant can use the “coded phrase” to call his co-worker and ask for help.

**Be alert.** Data collectors should be aware of their surroundings. If a threatening situation arises, they should remove themselves from the location immediately, albeit carefully and with a “cool head”. They should approach every potential respondent as though he is welcoming, but they should be cautious if there are concerns about an individual.

**Use common sense.** Data collectors should avoid wearing valuables or carrying large amounts of cash. They should not leave project materials in a car unsecured or in plain sight.

**Aggressive and/or threatening individuals.** If a data collector is directly confronted by an individual, he should employ de-escalation techniques: positioning to create extra space; do not smile: let the individual vent; listen to and acknowledge the individual’s concerns; avoid becoming defensive; use a lower voice, tone and tempo; respond to valid complaints.

**Sexual harassment.** If a respondent is sexually coming on to or harassing a data collector, the collector may terminate collection with that individual. If the data collector feels that the respondent is behaving inappropriately, he should first remind him that he is only there to interview the respondent and is not interested in sex, and second, if the respondent persists, he should state that the collection is going to be terminated if the respondent cannot stay focused on the actions requested. If this does not work, the data collector should terminate the interview.

**Drunk, high or drowsy respondents.** People who look unable to participate correctly due to particular states of mind should be avoided, partly for ethical reasons: a person who is too drunk or high could be unable to understand what is required and cannot
provide valid informed consent. It may not immediately be obvious that the respondent is unable to do what is required of him. In this case the data collector should not force him to complete the procedure, should stop the collection, thank him for his time and keep what has been completed (oral fluid and/or questionnaire) as valid but incomplete material. These situations should be recorded with the relevant barcode for the respondent.

4.3. Research toolkit

**Coordinators** will be provided with:

1. **Adhesive roll with number codes**: the series comprises 4 tags with the same code number separated one from another by one blank tag. The first step is the responsibility of the coordinator who should cut the sticker roll, divide up the series of tags and hand them over to data collectors according to the precise number to be handed over to each.

2. **VDT/Data collectors form**: form summarizing the number of collections assigned to every pair of data collectors according to the sampling plan (Annex 1)

3. **Record form**: form recording codes of questionnaires with relevant code and name of interviewers, VDT and date of collection - a copy will be sent to Sweden with the questionnaires (Annex 2)

4. **Oral-fluid sample delivery receipt**: receipt form to be filled in and signed by the person in charge of the laboratory, indicating the number of samples received (Annex 3)

Coordinators will provide the **data collectors** with the necessary tools, which include:

1. **Tags**: the data collector will receive the code numbers series already cut one from another by the coordinator.
2. **Informed Consent Form**: a form informing respondents about the contents and procedures of their participation in the research, including their signature for consent (Annex 4)

3. **Oral fluid collectors**: to be used directly by the respondent for oral fluid collection and delivered to the coordinator within 72 hours.

4. **Card**: to be given to the respondent once the oral fluid sample has been collected (Annex 5)

5. **Questionnaire**: to be filled in directly by the respondent and given to the coordinator.

6. **Info Pack**: to be distributed for the dual purpose of the campaign for prevention and of the approach for the research and developed by WP8 leaders.

7. **Scratch card**: A scratchcard is offered to a client after having filled in the Sialon II survey. The scratchcard may contain a question on sex behaviour, test behaviour, substance use and the transmission of HIV-STI (Annex 6).

8. **Information leaflet**: a brief note which informs respondents about project aims and contents (Annex 7)

9. **Refusal form**: a form where data collectors write the number of people refusing to Participate (Annex 8)

10. **Clipboards**

11. **Box for questionnaires**
12. **Refrigerated box:** box to be used if the environment is too hot for collecting oral fluid in a bag/box without damaging the samples.

13. **Bag for questionnaires and/or oral fluid collectors**

14. **Pens**

Before going to the data collection location, data collectors must get everything ready. Specifically, individual packs should be prepared for each respondent to cover the exact number of respondents (“respondent pack”), as follows:

- The 4 tags with the same code: one is stuck to the Consent Form, one to the questionnaire and one to the Card.
- The fourth tag is stuck to the oral fluid collector when handed over by the respondent. This tag should NOT be stuck on in advance because oral fluid collectors are in a sterile envelope which should be opened only in the presence of the respondent.
- Put the 3 tagged objects and the fourth tag into an envelope with the oral fluid collector.

Another tool can be prepared in advance for use at the data collection location: the “refusal form”. It should be put on the clip-board to be used only by the data collector. This can be used over and over again because only one sheet is needed for a number of different settings.

During data collection, but before approaching respondents, the data collector prepares the questionnaire to be submitted to the next respondent, removing a consent form and questionnaire from the plastic envelope and placing them on the clip-board, keeping the consent form uppermost since this is the first to be handed over. If it is likely that the questionnaire will be used shortly, the data collector may record the required data at this moment (Date, VDT, and Interviewer’s Code) in the space provided on the questionnaire. If not, to avoid confusion, it is useful to take
advantage of being in a pair, one data collector recording this data as the other makes sure the respondent provides a valid fluid sample rubbing the swab over the gums.

4.4. Approach and invite

Approach
During the widespread distribution of the “info-packs” as part of the prevention activities (see annex 10), data collectors systematically approach persons

- Systematically in practice means that subjects are approached as staff are available and ready to recruit.

Frequently, it will take personality and persuasion to get potential subjects to stop and agree to be screened for eligibility. Having lists of common reasons and retorts for nonparticipation is recommended. It is helpful to practice these responses in advance of sampling events (e.g., role play with staff).

Respondents need to be motivated to take part in the campaign for prevention, for example as follows:

“help gay associations in the struggle against AIDS and the prevention of STD, by taking part in this important transnational, European project. It could help public authorities do more (in terms of providing funding, taking or backing actions for prevention, etc.)”.

Eligibility and enrolment

In approaching men, recruiters should quickly identify themselves and their organization and succinctly describe their purpose.

“Hi, my name is (name) and I work for (organization). (Organization) is conducting an important health survey and I would like to ask you a few quick questions”.

“Excuse me, I am (name) from the (project name) project. We are conducting an important health survey and I would like to ask you five quick questions.”
If the respondent has not taken part before or is uncertain, a detailed explanation should now be given of who the participants are (men older than 18 years old who had sex at least once with another man during the last 12 months), what is being requested and the anonymity of the study (by showing the information sheet):

“We are inviting all men older than 18 years old who attend different gay venues in [city or country], who have had sexual relationships with another man at least once during the last 12 months and who have not already participate in the project previously. The questionnaire is to get an idea of the behaviour in relation to the risk of HIV and STIs and the sample is to test for HIV infection in the population. It is a questionnaire you must fill yourself, unseen by others, and will take no more than 10 minutes, plus a sponge/stick to rub against your gums for about 1 minut”.

The precise target (“men who had sex at least once with another man during the last 12 months”) is also described in the Consent Form which respondents will be asked to read next.

To avoid misunderstandings of various kinds it is important to say that the test is for research purposes and is not a rapid, diagnostic test, although the result can be given: the respondent cannot be given this result there and then but may ask of the result after some days. It should also be stated that if the respondent wants to know the test result, at the moment of giving him the result he will be asked for a blood sample to give an updated and certain result. At this point the anonymity of the questionnaire and test sample should be repeated, as for data processing:

“no names are used, questionnaires are matched to samples using a barcode (not a name). I’m asking you to sign the informed consent form, but you can also use any kind o mark you like without your using real name, You don’t need to show any kind of document, it is just a formality that is required to show the importance of consent. When you go to pick up your test result all you need is the Card and barcode we will give you, so the results too are anonymous.”

Migrants and tourists will be able to be included if the questionnaire is understandable (only people able to fill in the questionnaire by themselves should be included). If the
respondent refuses to take part, the refusal will be recorded on the “refusal form”. If the respondent agrees to take part, the interviewer will show him the clip-board with questionnaire and consent form. The respondent should read it and sign it anonymously, making a mark.

4.5. Complete survey

Eligible men who agree to participate have to fill in the questionnaire after signing the informed consent.

Remind the respondent that he must fill in the questionnaire alone. While the respondent is filling in the questionnaire, the data collector should limit himself/herself to briefly clarifying any questions and providing general assistance.

For the interpretation of questions see questionnaire manual (Annex 8); do not make personal interpretations and if in doubt contact your coordinator.

When the respondent has finished filling in the questionnaire, the data collector takes it back and places it, in front of the respondent, into the bag or box. This underlines privacy and confidentiality, i.e. ensures that the data collector sees none of the answers. Alternatively hold the bag or box out to the respondent so he can put the questionnaire into it.

4.6. Specimen collection

After the questionnaire, oral fluid samples should be collected.

- Give the respondent the sterile package and tell him he should open it so he can see for himself that it was sealed and container sterile material.
• After opening the package, the respondent should take out the sampling stick.

• The swab should be rubbed back and forth over the upper and lower gums, 30 times to the right, 30 to the left: make sure the respondent does this properly. Specifically, the swab should be primarily rubbed against the gums and not the teeth in order to obtain enough oral fluid to analyze in the lab. **The success of the entire research project depends on this, because insufficient oral fluid would make it impossible to meet the primary aim of the research,** which is to determine the prevalence of HIV and syphilis.
• The respondent should then close the test tube himself and hold it for a moment to allow the data collector to stick on the fourth tag with barcode. The tag should be stuck on **vertically**, i.e. with the bar code along the length of the test tube and not around its circumference, to prevent later problems of reading the barcode by optical instruments.

![Image of test tube being closed and tagged](image)

• When the respondent hands back the test tube the data collector hands over the card required to pick up the test result. It is important to remind the respondent to keep the Card with barcode on him; it is the only means of picking up the test result: only the barcode identifies the person providing the sample.

![Image of test tube and card being returned](image)

• At this time, explain or repeat that:

  - the result will be ready no later than in 1 week after saliva collection. In the case the test results will be reactive the 2\(^{nd}\) test from saliva or blood should be performed.
  - the respondent should call the number on the card at the times shown and say he is calling “for the Sialon result”;
- a test will be carried out in line with WHO/UNAIDS rules and any local statutory requirements or requirements of the local screening centre.

- The test tube should immediately be placed back in the bag or fridge box, depending on environmental temperature.

4.7. Prevention activities (Annex 10)

Personal interaction makes it possible to adapt the information to the personal needs of the respondent. The interaction will be tailored to the individual prevention needs of the respondent by means of a scratchcard/quiz. This scratchcard is offered to respondents after data-collection. The scratchcard can contain a question on sexual behavior, HIV/STI testing behavior, substance use and HIV/STI transmission. The data collector reads the question and possible answers. The respondent chooses one answer and scratches the card (by data-collector or visitor) to reveal the answer. The data-collector briefs the respondent on the right answer.

4.8. Counseling / Referrals

After data collection, respondents will be offered the possibility to subsequently pickup their results in a VCT centre and a test on blood will be offered for HIV according to the national guidelines. Test for Syphilis, HBV and HCV will be offered
where possible. If not, information on where to go in order to perform these additional tests using the national health care service provision system will be done. He will receive a pre-post test counseling and treatment according to local standards. The target group will also find additional information on the project website. The project website will function as a hub for local prevention and intervention projects by Sialon II partners. This method will provide respondents and others that come upon the website with a culturally tailored prevention and intervention response.

4.9. Transportation and storage of oral fluid samples

During collection of oral fluid samples, they should be kept at ambient temperature and then placed in the fridge as soon as possible (not in a freezer) if not handed over immediately to the coordinator. Keep temperature changes in mind, since they could damage the samples (for example, if it is sunny and hot, use the fridge box). Samples must be handed over within 72 hours to the coordinator and must not be frozen by the data collector: this is the coordinator’s job, if required, according to the instructions of the local lab.

4.10. Delivery of oral fluid samples and questionnaires to coordinator

Oral fluid samples and questionnaires should be handed over together to the coordinator, who records delivery on the record form [ANNEX 2] specifying in single (number X) or aggregate form (from number X to number Y) the codes of questionnaires and samples handed over, the code for the del data collector, place, date and time of data collection and date of delivery. The data collector signs off the delivery: no hard copy receipt is provided, but his signature appears on the Record Form enclosed with the questionnaires when the coordinator sends the materials to Verona, hence it is possible to see who did what.
Table 1 Procedure for Data Collectors

- MSM participants approach and recruitment
- Prevention, information and materials
- Description of the study (inclusion criteria)
- Preliminary verbal consent
- Information sheet, informed consent signature
- Bio-behavioural data collection
- Anonymous card for referral
- Prevention activities (scratch card)
- Enrollment (yes)
- Refusal form (no)
- End

2.5.3 Participant recruitment
- 2.5.6.2 Innovation in service delivery
- 2.5.3 Participant recruitment
- 2.5.7 Admission procedures
- 2.5.6 Description of intervention
- 2.5.6.1 Drugs and devices
- 2.5.8 Follow-up and procedures
5. Monitoring and evaluation

The prevalence of HIV and the data received from the questionnaire are to be published at the website www.sialon.eu.

The evaluation of the data collection and prevention on the spot itself will be done the evening itself. The coordinator asks the following questions:

1. How did it go?
2. What kind of questions did the participants have?
3. Was it easy to participants?
4. Did you feel safe?
5. How were the circumstances (noise/temperature etc)?
6. Did you feel supported by the coordinator?
7. How was the collaboration with the staff?
8. High- and lowlights of the day?
9. Actions of improvement: who should do what and when?

If necessary, the coordinator and data-collectors can adjust items to be evaluated. The evaluation is reported in the following table by the coordinator (Table 3). Actions of improvement are noted.
### Table 3

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Data-collectors and coordinator present:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. How did it go?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. What kind of questions did the participants have?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Was it easy to recruit participants? Yes, no, explain?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Did you feel safe?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. How were the circumstances (noise/temperature etc)?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. Did you feel supported by the coordinator?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. How was the collaboration with the staff?</td>
</tr>
</tbody>
</table>
8. High- and lowlights of the day.

9. Actions of improvement: who should do what and when?
Annexes:

Annex 1. VDT/Data collector form
Annex 2. Record form
Annex 3. Oral-fluid sample delivery receipt
Annex 4. Informed consent form
Annex 5. Card
Annex 6. Scratch card
Annex 7. Information sheet
Annex 8. Refusal form
Annex 9. Questionnaire manual