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STRATEGIC PLAN
TO ENSURE SUSTAINABILITY OF INTEGRATED BIO-BEHAVIORAL SURVEY IN UKRAINE (2018-2021)

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STRATEGIC PLAN TO ENSURE SUSTANABILITY OF INTEGRATED BIO-BEHAVIORAL SURVEY IN UKRAINE

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CONTENT

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LIST OF ABBREVIATIONS

AIDS	-	Acquired immunodeficiency syndrome
AIDS center	-	Center for AIDS Prevention and Control
ART	-	Antiretroviral therapy
CDC	-	Center for Disease Control and Prevention
DBS	-	Dried blood spot testing
GF	-	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	-	Human Immunodeficiency Virus
IBBS	-	Integrated Bio-Behavioral Survey
KG	-	Key group
MSM	-	Men who have sex with men
NGO	-	Non-governmental organization
PEPFAR	-	United States President's Emergency Plan for AIDS Relief
PHC	-	State Institution “Public Health Center of the Ministry of Health of Ukraine”
PLHIV	-	People living with HIV
PWID	-	People who inject drugs
RDS	-	Respondent-Driven Sampling
RT	-	Rapid rest
SOP	-	Standard Operation Procedures
SW	-	Sex worker
TLS	-	Time-Location Sampling
UNAIDS	-	Joint United Nations Program on HIV/AIDS
UNDP	-	United Nations Development Program
UNICEF	-	United Nations International Children’s Emergency Fund
UNODC	-	United Nations Office on Drugs and Crime
VH	-	Viral hepatitis
WHO	-	World Health Organization

1 INTRODUCTION

Effective overcoming of the HIV epidemic requires timely and reliable information on the HIV prevalence among HIV/AIDS representatives of key groups (hereinafter KG), in particular, people who inject drugs (PWID), sex workers (SW), men who have sex with men (MSM). The WHO/UNAIDS Guide for Second Generation HIV Surveillance identifies sentinel surveillance among the KG as an important tool for obtaining a realistic assessment of the epidemic situation and the development of measures to overcome the epidemic. The size of KGs and risky behaviors of their representatives affect the epidemic tendencies and intensity, as well as cause the spread of HIV among general population.

The routine surveillance system does not provide complete and accurate information on the main epidemic indicators - the HIV incidence and prevalence in the KGs. The program data neither evaluate to a full extent the factors and features of risky behavior in the context of HIV infection, nor provide information on the coverage of the representatives of KG by prevention and treatment measures.

For today, the most recommended approach for obtaining such strategic data is carrying out integrated bio-behavioral survey (IBBS). The systematic conduct of such studies provides monitoring of HIV prevalence and risky behavior among the KGs; allows to develop and use tailored prevention programs and assess their effectiveness; analyze the cascade of services for KGs and people living with HIV (PLHIV); and identify new vulnerable to HIV infection population groups and foresee trends of epidemic process development.

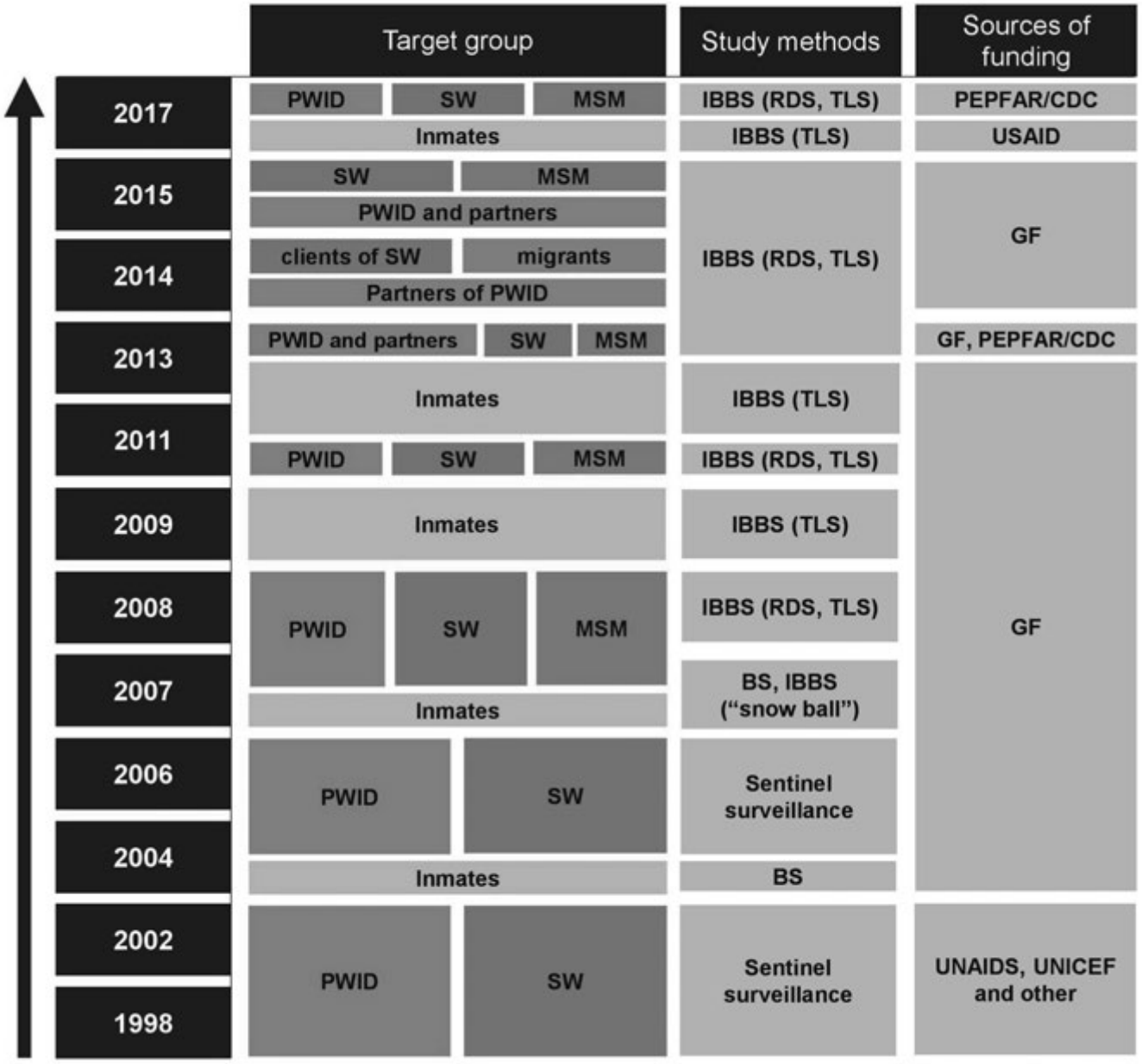
The main goal of IBBS is to obtain a comprehensive evaluation of the epidemic process of HIV infection among the KGs and provide qualitative information to provide for planning and implementation of preventive and anti-epidemic measures.

IBBS is a strategically important public health tool and has a number of key objectives, namely: to assess the HIV spread; identify the features of behavioral practices associated with HIV; analyze the effectiveness of the implemented preventive and therapeutic measures, including cascade of sevices; estimate the HIV incidence; calculate the population of the key group representatives who took part in IBBS.

Since 1998, sentinel epidemiological surveillance among KGs has become an integral part of epidemiological monitoring component in Ukraine, and initially has been conducted by the Ukrainian Center for AIDS Prevention and Control of the Ministry of Health of Ukraine (currently the State Institution "Public Health Center of the Ministry of Health of Ukraine") with support of various international agencies - WHO, UNAIDS, UNICEF, UNDP. Since 2007, IBBS has been implemented by the efforts of the ICF "Alliance for Public Health" within the framework of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF), PEPFAR, UNOCD.

As Ukraine is committed to implement a transition to state budgeting within the framework of Sustainable Response Strategy to tuberculosis epidemics, including DR TB, and HIV/AIDS for the period up to 2020, as approved by the Order of the Cabinet of Ministers of Ukraine dated 22.03.2017 No. 248-p., a Transition plan 20-50-80 stipulates a phased transition of financing responsibilities to cover health programs from external donors (mainly GF) to state funding and funding from local budgets and supposes an allocation of bigger proportion of public funds for the IBBS conduction. The responsibility for the IBBS implementation should be assigned with the State Institution "Public Health Center of the Ministry of Health of Ukraine" (the PHC). This will contribute to the sustainability and institutionalization of the IBBS conduction as a component of the National Strategy for Countering HIV/AIDS.

The main stages of development of sentinel epidemiological surveillance in Ukraine, in particular the implementation of the IBBS (1998-2017)



The Strategic Plan for Ensuring Sustainability of Integrated Bio-behavioral Studies in Ukraine (Strategic Plan) is a consolidated guide on the IBBS conduction in Ukraine, which takes into account the latest international recommendations and developments on the methodology and implementation of such studies at the national and regional levels. The Operational Plan for integrated bio-behavioral studies conduction among key population groups goes with a Strategic Plan.

This goal of this document is to ensure the qualitative conduction of IBBS, and the provision of relevant data that will help in a managarial decision-making in the sphere of public health, as well as contribute to the improvement of preventive and curative services, efficient allocation of resources and effective policies development to overcome the HIV epidemic in Ukraine.

The target audience of this Strategic Plan includes the IBBS team of the PHC, National working group on the IBBS conduction in Ukraine, international and national stakeholders in the field of HIV/AIDS counteracts, donor organizations and the international technical assistance projects.

Timeframe for the Strategic Plan realization: October 2018 - December 2021.

During April-August 2018, the draft document was discussed at working meetings with a participation of representatives of the Centers for Disease Control and Prevention (USA, Atlanta) and the International Center for Health Education and Training, Department of Global Public Health, University of Washington, DC (I -TECH/UW PEPFAR). In October 2018, the document was forwarded to the interested parties for approval and finalization.

The Strategic Plan has been developed by the PHC specialists within the SILab Project " Support for the Ministry of Health of Ukraine HIV Epidemiological Surveillance and Laboratory QM/QI systems, SI, and Public Health Capacity Building under the President's Emergency Plan for AIDS Relief (PEPFAR)".

2 IBBS METHODOLOGY

The IBBS has a cross-sectional design, that is, single time data slice, and when conducted regularly allows monitoring of the tendencies of HIV prevalence and risky behavior among KGs. The algorithm of the IBBS conduction involves **6 consecutive stages**, specifically:

(1) formative assessment;
(2) formation of a representative sampling strategy;
(3) participants screening;
(4) behavioral data collection;
(5) biological data collection;
(6) compensation payments to participants.

1. A formative assessment is carried out in order to: understand the target group and the context of its further study in a specific region; identify available HIV prevention services and gaps in this system; determine the optimal strategy for information collection; attract regional stakeholders. During the in-depth interviews with the representatives of the NGOs and the representatives of a target group, the research team will learn about: specific characteristics of the target group, social environment and the place of potential concentration of participants, their personal network and the possibility to reach the target sampling size, sexual and injection practices of the target group representatives, law enforcement actions in relation to the target group. The objectives for further stages of formative assessment depend on the potential method of sample formation and recruitment of study participants, but it is the results of the formative assessment that determine a specific strategy for data collection.

2. Formation of a representative sampling strategy. Take into account the characteristics of the target group when selecting the strategy for sample formation.

Factors for choosing a formation strategy for the IBBS representative sampling

	THERE IS NO SAMPLING FRAME	NO CLOSE LINKAGE WITHIN THE GROUP	GROUP MOBILITY	GROUP'S ACCESSIBILITY TO THE LOCATIONS AT THE TIME INTERVAL
SRS Simple Random Sampling	-	+/-	-	+/-
CCS Conventional Cluster Sampling	+	+/-	+/-	+
RDS Respondent-Driven Sampling	+	-	+	-
TLS Time-Location Sampling	+	+	+	+

Differencies between RDS and TLS as representative sampling formation strategies

	RDS – Respondent-Driven Sampling	TLS – Time-Location Sampling
FORMATIVE EVALUATION WITH THE FOCUS ON...	Information collection on the criteria for primary respondents (seeds) and relevant sites for interviewing and testing. Identifying 2-4 seeds in one locality, access to whom is provided by key informants. Additional seeds are selected during data collection in case the process is slow or there is a discontinuation of recruitment in chains.	Collection of information on the target group concentration locations with their further mapping and validation. Determination of the point type, the number and the potential respondents' socio-demographic profile, the point's opening hours and seasonality, the accessibility to data by a collection team, safety level at the point and the need for a guide, the point coverage by the prevention programs. Transport selection to visit the points (mobile outpatient unit or other transport, which is specially equipped and meets technical requirements).
RESPONDENTS RECRUITMENT	Recruiting the respondents from one wave by the respondents from another wave is conducted by using a mathematical model, that eliminates shifting through non-random selection. Each respondent receives 3 coupons, which are then passed on to other representatives of the target group in their social network. RDS coupons contain an individual number of the respondent and are registered in a special software for further recruiting network construction.	Recruiting by the member of the data collection team at the target group concentration sites. The research team possesses a sampling frame by location and time and selects sites to conduct a study. According to the list of selected sites, the regional team creates a schedule of its work and visits each site

Within the RDS use, regardless of the number of primary seeds (two or more), the research team must provide a variety of their characteristics.

Selection criteria for primary seeds within the IBBS according to the RDS strategy

	Primary seed 1	Primary seed 2
Motivation to participate in the study	Motivated to participate in the study and disseminate information about it among the target group representatives	
HIV status by self-declaration	Positive HIV status	Negative HIV status
District of residence	District X	District Y
Age category	Up to 19 years old	Above 20 years old
Prevention programs participation	Client	Not a client
Socio-economic status	Low	High
The social network size	The social network of acquainted representatives of the target group is at least 7 people	

Study sites (premises) selection must meet a number of criteria, particularly:

(1) convenient and accessible location;

(2) sufficient number of waiting rooms, rooms to conduct interviews, testing, pre-and post-test counseling;

(3) comfortable and convenient interior (for example, the presence of heating/cooling systems);

(4) the remoteness from the place of the provison of HIV prevention and treatment services.

The same room is used to conduct survey of one KG for one time period. During the formative assessment, in large communities, the need for several sites will be specified to enable a wider coverage of the target group representatives.

3. Participants screening determines whether a person belongs to a target group and meets its inclusion criteria. The inclusion/exclusion criteria are specified in the Study Protocol and Standard Operating Procedures (SOPs) for recruitment and screening. Each participant of a particular target group should have features that reflect the characteristics of the general sampling, and be identifiable among other groups.

Inclusion and exclusion criteria for PWID, SWs and MSM respondents of the IBBS

	PWID	SW	MSM
INCLUSION CRITERIA	Age - 14 years and older at the time of the study		
	Duration of residence/work/ training in the area of where survey is conducted for at least past 6 months		
	Consent to take part in the study		
	Injecting drug use during the last 30 days	Exchanged sex for compensation in the past 6 months	Oral or anal sexual contact with a man within the last 6 months
EXCLUSION CRITERIA	Participation in one study round more than once		
	A degree of alcohol or narcotic intoxication that does not allow to understand and give answers to the questions from the questionnaire, and the respondent's behavior that endangers his own safety or the safety of others		

The participants' compliance with the inclusion criteria is established by the regional team on the basis of the representatives' self-declaration of belonging to the target group, visual inspection and clarification of certain details (for example, about the specific place of MSM gathering). The research team should be able to identify people who do not belong to the target group and be able to refuse their participation in the study. If the target group representative meets the inclusion criteria, he/she undergoes the procedure of signing the informed consent, and his/her coupon is registered in the accounting system.

4. Behavioral data collection

Behavioral data is planned to be collected via filling in online questionnaire using tablets. The electronic toolkit has a number of advantages, in particular:

(1) no need to transfer data from paper questionnaires into the database;

(2) ensuring a unified survey approach for all respondents;

(3) the convenience of filling out an electronic questionnaire (for example, automatic

switching between questions, language selection) and the availability of logical control of the input data;

(4) no need for additional costs (e.g., printing of questionnaires);

(5) instant and easy data export for further analysis.

The research sites should also maintain printed versions of questionnaires in case of possible problems connected with the electronic application (absence of a screening, system freezes or stops responding during data entry, incorrect fixation of remuneration payments). In case of no/poor Internet connection, the team uses printed questionnaires and transfers the data after the completion of a working day on the site at the same day.

5. Biological data collection

The biological component of the study may include screening testing using rapid tests (RT) on the presence of HIV serological markers, parenteral viral hepatitis B and C (HBV and HCV), STIs and tuberculosis; confirmation testing performed using rapid tests for participants with a positive HIV test result of the first RT; DBS to detect recent HIV infection and HIV viral load.

Algorithm on the collection of biological data within the IBBS

1. PRE-TESTING COUNSELING	Conducted in accordance with the National Protocol on HIV testing services Includes brief information on the main transmission ways of HIV, VH; confidentiality and test result values, preventive measures and free treatment.
2. TESTING USING RAPID TESTS	Foresees screening testing using the first RT on the presence serological markers of HIV, hepatitis C and other infections as determined by the IBBS Protocol, confirmation testing using rapid tests for the participants with a positive HIV test result of the first RT
3. DRIED BLOOD SPOT TESTING	Used to detect recent infection and viral load. Conducted for the participants with positive HIV test results as well as for 10% of participants with a negative HIV test result selected randomly. Analyzed using LAg-test.
4. POST-TEST COUNSELING	Conducted in accordance with the National Protocol on HIV testing services Includes an explanation to the participant of his/her test results
5. REFERRAL TO TREATMENT	Implemented for all participants with a positive HIV test result, confirmed by the second test, by referral to the primary healthcare facilities for further registration, prescription of antiretroviral therapy and involvement into the projects of case management, care and support.

6. Payment of compensation to respondents

After completing the survey and testing, the participant receives compensation for his/her participation in the study. Depending on the sampling strategy, one or two types of compensation are provided, in particular: representatives of the target group receive compensation for the time spent and/or travel expenses as the respondents of the study; participants receive reward for recruiting the target group representative that meets the inclusion criteria when using the RDS methodology.

3 SITUATION ANALYSIS

According to the results of the study "Assessment of the HIV/AIDS surveillance system in Ukraine", conducted in 2018 within the framework of SILab Project (CDC, PEPFAR), the conduction of preliminary IBBS rounds among the three key groups: PWID, SW, MSM was analyzed.

Quality assessment of the IBBS conduction in Ukraine (2015-2018)

The strengths of the IBBS past rounds, in particular since 2015	Spheres for improvement in the future IBBS rounds
Meet the international recommendations on the survey format, compliance with the ethical standards, quality assurance and data analysis approaches.	The IBBS financing is carried out exclusively by international donors, without the involvement of state funds
	The criteria of belonging to the KG need to be reviewed at the national level
Representative results fully describe the existing involvement characteristics of the representatives of three key groups in the HIV epidemic process : PWID, SW, MSM	The bio-behavioral characteristics of non-injecting drug users are practically unknown. There is a shortage and limitation of available data regarding sexual partners of PWID, SWs' clients and representatives of the general population within the territories with mixed HIV epidemic. There is no bio-behavioral study data on the characteristics of the key population groups in rural areas.
The recommended sampling methodologies RDS and TLS are used; the choice to use them in IBBS among representatives of SWs was based on the results of formative assessment	The method of sampling formation for PWID, MSM is not based on formative evaluation. There is no justification for sampling size to calculate the recent HIV infection indicators
	Incompliance with the beginning terms of the study's field stage
	Some criteria of primary seeds inclusion for the RDS method may limit the sampling representativeness (age limit, HIV-negative status)
Participants with a positive HIV test result are referred to AIDS Centers and the feedback on their reaching the destination site is provided	Serum markers for STIs, hepatitis B and hepatitis C (for MSM group) are not identified.
Data analysis is performed using a specialized statistical RDS-Analyst package, which improves the quality of the obtained results.	Some reports lack mapping methods when presenting the study results
	Large time interval between the receipt of study results and the publication of reports (year and more), which diminishes the data relevance
	Lack of full operational access to data arrays of all IBBS rounds in Ukraine

An issue of quality of conducting estimation of the number of PWID, SWs, MSM, used to calculate the IBBS data, was also focused on within the "Assessment of the HIV/AIDS Surveillance System in Ukraine".

Assessment of the quality of conducting estimation of the number of target groups' population in Ukraine (2013-2017)

The strengths of past studies on assessment the key groups size	Areas for studies improvement on key groups size assessment
The obtained indicators provide an understanding of their potential role in the HIV epidemic development in Ukraine	Limitations of the list and the criteria of belonging to key groups, defined at the national level, make it difficult to use them during the assessment.
Carried out regularly, its frequency is in compliance with the international recommendations.	The fact that the estimation of the number of SWs clients and sexual partners of PWID has not been conducted in recent years, makes it impossible to provide a more comprehensive picture on the role of key groups in HIV epidemic development in Ukraine
The conduction of study in all oblast centers of the country, in Kyiv and the Autonomous Republic of Crimea provided with a possibility to make estimates in each oblast of Ukraine.	The calculation of estimated population size using the generally recommended methodologies was carried out only at the city level (with the assumption that this restriction is compensated by a greater prevalence of risky behavior mainly among urban population)
The use of WHO and UNAIDS recommended methods for the assessment of the risk groups population and obtaining an averaged indicator of the separate risk groups population increases the quality of the obtained results.	The application of the methodology "repeated coverage" using data from the other two IBBS rounds is not substantiated due to the long time interval between studies (2 years)
	The decision on the final criterion for a selection of evaluation range for each of the target groups was made by expert assessment, risking the possibility of biased results.
The electronic version of the 2017 study report is available for download, providing the necessary public access to the study results.	The 2017 report does not provide mapping data thus complicating the perception of territorial features
The estimated data on the key groups has been approved by the majority of the coordination councils which is a good indication of the effective use of the obtained results.	Regional experts do not have information on data arrays access procedure that have been used for when determining evaluation indicators and intermediate estimates, which limits the possibility to validate for the evaluation indicators when getting their approval at the oblast level

4 STRATEGIC DIRECTIONS

The process of developing proposals on the change of policy based on strategic information, corresponds to the function of a unified system to monitor and evaluate the effectiveness of measures (M&E) aimed at preventing the HIV epidemic spread, according to the Resolution of the Cabinet of Ministers of Ukraine dated December 28, 2011 No. 1349. The IBBS, as part of a unified M&E system and a national HIV/AIDS surveillance system, requires institutionalization at the national level as the only way to ensure the sustainability of IBBS, taking into account the ongoing reduction of donor funding.
The key directions of the IBBS institutionalization at the national level are as follows: create a regulatory basis for study conduction, including the national IBBS procedure development; establish a national coordination mechanism for the study management on the PHC basis and strengthen the capacity of the National Reference Laboratory for the HIV/AIDS diagnosis.

In order to institutionalize the IBBS conduction in Ukraine, the PHC and the National working group on the IBBS implementation need to undertake the following strategic directions:

1. IBBS optimization;
2. Reduction of the required financial resources for the IBBS conduction;
3. Increasing the level of the IBBS data use;
4. Strengthening of potential of the PHC staff, in particular, its procurement potential.

STRATEGIC DIRECTION 1
IBBS OPTIMIZATION

Objective 1.1. Prioritization of target groups for IBBS conduction

In the context of national policies and the HIV epidemic response measures, two groups related to the HIV infection are distinguished - the key and the vulnerable groups. Key groups (KG) include those that are at increased risk to HIV infection due to their behavioral practices, have a significant impact on HIV spread dynamics and play a key role in effectively counteracting the HIV epidemic (regardless of epidemic type or local conditions). According to the UNAIDS definition, the key groups of HIV infection high risk include PWID, SWs, MSM, transgender people, convicts and people in detention facilities. According to the Order of the Ministry of Health of Ukraine No. 104 dated February 08, 2013, "On approval of the list and criteria for determining the high risk groups for HIV infection", the groups of HIV infection high risk include: PWID, SW, MSM, sexual partners of PWID, clients of SWs, sexual partners of MSM.

The so-called **vulnerable groups** include those becoming more vulnerable to HIV than the general population due to inequal opportunities, social stigma and segregation, unemployment, shady or unstable employment, and other social, cultural, political and economic factors. Vulnerable groups

may include migrants released from places of detention, street children, servicemen, long-distance truck drivers, etc.

Measure 1.1.1. The IBBS conduction on a regular basis in the KGs with HIV infection high risk according to the such groups list, approved under the legislative framework (PWID, SW, MSM, others).
Measure 1.1.2. Initiatiate a discussion on the IBBS feasibility performance among non-injecting drug users who may also have risky HIV infection behavior.
Measure 1.1.3. Inclusion of additional target groups into future IBBS rounds after obtaining evidential basis on the presence of HIV infection high risk.

In order to determine the feasibility of the IBBS conduction in a target group, the IBBS National Working Group takes into account a number of aspects, namely: the role of the KG in the HIV infection epidemic and the HIV prevalence in the group; estimating the group size and the ability to reach the calculated sampling size; HIV infection risk factors; support for local organizations and willingness to cooperate within research.

Possible changes	Preconditions
Revision of target groups for future studies with National Working Group on the IBBS conduction in Ukraine	Amendments to the Order of the Ministry of Health of Ukraine as of 08.02.2013 № 104 "On approval of the list and criteria for determining the high risk groups of HIV infection"
IBBS conduction among vulnerable groups unprovided by the Strategic Plan	Initiation of the IBBS by groups that have a significant impact on the HIV epidemic development and require an evidence base for advocating their rights, making political decisions and programs and projects planning.
Conduct special studies among vulnerable groups	Need for evidential data on the presence of high risk of HIV infection; insufficient size of the target group within the populated area for the IBBS conduction

Objective 1.2. Prioritization of the regions for the IBBS conduction in Ukraine

Previous IBBS rounds among PWID, SW and MSM have been held in administrative centers of all Ukraine's oblasts, and since 2015 - in cities of oblast significance with a predicted sufficient number of KG representatives.

Measure 1.2.1. IBBS conduction for specified KGs (PWID, SW, MSM, others) in a smaller number of settlements, where it is possible to reach the estimated sample size of 500 persons (according to CDC recommendations).
Measure 1.2.2. Ensuring the data collection and analysis on the defined KGs (PWID, SWs, MSM, others) in the regions where it was decided not to conduct the IBBS round based on the results of program monitoring, routine surveillance and within operational studies.

The possibility of including each oblast into the study is based on: the epidemic situation; lack of sufficient information on the HIV morbidity among the KG; sufficient size of the KG in the region to achieve the estimated size of the random sample.

Possible changes	Preconditions
IBBS conduction in the Autonomous Republic of Crimea, Sevastopol and the territories of Donetsk and Luhansk oblast temporarily uncontrolled by the Government of Ukraine.	Stabilization of the political situation at the time of the study planning

Objective 1.3. Increasing the interval between IBBS rounds in Ukraine

Measure 1.3.1. IBBS conduction among transgender people in 2018-2019 through sub-grant of a research organization at the GF expense within the project "To accelerate the reduction rates of tuberculosis and HIV incidence by providing general access to timely and qualitative diagnosis and treatment of tuberculosis, by expanding the evidence-based medical prevention, diagnosis and treatment of HIV and the establishment of a sustainable and viable health care system".
Measure 1.3.2. IBBS conduction among the PWID in 2020.
Measure 1.3.3. IBBS conduction among CWs and MSM in 2021.
Measure 1.3.4. Planning of the IBBS among convicts in 2022 and among PWID and transgender people in 2023.

Possible changes	Preconditions
IBBS conduction at other times than specified in the Strategic Plan	The result of consultation with national and international experts; availability of sufficient financial resources

Objective 1.4. The increase of the sample population size within the region

Due to the correct size of the sample population it is possible to: estimate the prevalence of a particular characteristic in a specific time slice in a specific place with a predetermined level of accuracy (for example, the HIV prevalence among the SWs in Zaporizhzhia); reveal the differences in characteristics prevalence between the two groups or time intervals (for example, the HIV prevalence among the SWs in Zaporizhzhia and Kyiv or the HIV prevalence among the SWs in Zaporizhzhia in 2013 and 2017).

Measure 1.4.1. Calculation of the sample size based on the "viral load" variable.
Measure 1.4.2. Increasing the sample population size within each region to assess the viral load level.

Objective 1.5. The time gap optimization between the study stages

Measure 1.5.1. Reducing the time interval between the conduction of the training sessions, formative assessment and data collection.

Measure 1.5.2. Increasing the timeframe to select premises for study sites.

Measure 1.5.3. Conducting the field stage during two-three months depending on the target group, sample population and geography of the study.

Measure 1.5.4. Conducting data processing and analysis along with data collection accordingly to the pre-developed Data Analysis Plan and preparation of RDS-Analyst codes.

Objective 1.6. Field stage optimization of the IBBS conduction

Measure 1.6.1. Survey of the participants about those representatives of the target group who were invited to participate in the study, but they refused to receive coupons (during site visiting to receive compensation for recruiting).

Measure 1.6.2. Survey of the participants who refused to answer the modified questionnaire with a focus on the reasons for refusal (with prior approval for remuneration size).

Measure 1.6.3. Changing the form of questions that were "difficult" to understand during previous rounds of survey (for example, answer options regarding the question on ART (antiretroviral therapy) regimen which the participant of the study receives, it might be used the photo-images of drugs included in this regimen instead of the written textual form (TDF/FTC + EFV).

Measure 1.6.4. Approbation of self-survey among MSM by using IBBS questionnaire audio reproduction.

Measure 1.6.5. Increasing the tracking level of HIV-positive participants to the health institutions providing medical care-related to HIV (AIDS centers), medical facilities of other profiles and levels of medical care provision) by obtaining contact details of such participants subject to their voluntary consent.

Measure 1.6.6. Implementing a system of respondents' preliminary record and/or biomaterials sampling when informing a participant about a secondary respondent recruiting in order to avoid queues and minimize the time of the participants presence on the site.

Measure 1.6.7. Establishing a differential remuneration for participating in the study depending on the term of a coupon receipt by the participant prior to the site visiting (for example, the participant who came to the site during the first week after receiving the coupon gets compensation more than the participant who came in three weeks) to minimize uneven recruiting by RDS method.

Measure 1.6.8. Conduct a special lottery to attract the target group representatives with high income.

Measure 1.6.9. Installation of "anonymous mailbox" in the site's premises for study participants to receive feedback on the field studies organization and IBBS optimization during further planning.

Possible changes	Preconditions
Expanding the content of the IBBS questionnaire blocks (e.g., evading to use health services because of stigma and discrimination)	The consultations result with national and international experts, initiation the relevant changes by the representatives of the target groups
Testing for active syphilis, HBV and STIs for reporting on monitoring and evaluation indicators (e.g., GAM-Global AIDS Monitoring)	Availability of sufficient financial resources
Change of the testing algorithm by rapid tests	Adoption of the draft order of the Ministry of Health of Ukraine "On improving the quality management system of laboratory research in the field of HIV / AIDS counteraction" (Amendments to Order No. 1141)
Developing an algorithm for redirecting participants with a positive test result for HCV	Amendments to the Strategy for the prevention, diagnosis and treatment of viral hepatitis B and C by 2020
HIV testing by non-medical worker	Adoption of the draft Law of Ukraine "On amendments to certain legislative acts of Ukraine in the field of counteraction to the diseases spread caused by HIV"

Objective 1.7. Evaluation optimization of key groups representatives number in Ukraine

Захід 1.7.1. Usage of databases of prevention programs clients in Ukraine such as SYREX (ICF "Public Health Alliance") and Case ++ ("All-Ukrainian Network of people living with HIV"), with further data triangulation between them.

Захід 1.7.2. Data use on the hospitalized persons to narcological clinics as the data on PWID, given the lack of PWID separate registration in the general registry of the hospitalized.

Захід 1.7.3. The change of the restrictive minimum quantity of PWID in the indicator of the group representatives coverage with preventive services for the hospitalization statistics to the narcological clinics.

Захід 1.7.4. Initiating discussion on the possibility to assess the KG representatives number at the rural level, taking into account the assumption of risky behavior prevalence mainly among the urban population.

Захід 1.7.5. "Unique object" technique approbation for estimating the number of KG representatives in Ukraine.

Захід 1.7.6. Conduct the mapping of the KG representatives number to increase the assessment results visualization.

STRATEGIC DIRECTION 2
REDUCTION OF FINANCIAL RESOURCES NEEDED FOR IBBS IMPLEMENTATION

Objective 2.1. Use of available resources in the regions

Measure 2.1.1. Provision of communal property premises for research sites through a dialogue with local authorities.

Measure 2.1.2. Use of potential of the regional training centers and NGO's premises for the training of regional teams.

Measure 2.1.3. Involvement of regional specialists in monitoring visits within a region of research.

Objective 2.2. Reduction of IBBS administration costs

Measure 2.2.1. Implementation of webinars and skype-calls for operational meetings.

Measure 2.2.2. Inclusion of questions from stakeholders into a IBBS questionnaire on a fee basis to cover costs.

For the sources of funds and mechanisms for ensuring the financial sustainability of the implementation of the IBBS in Ukraine see section 7. Financing the Implementation of the Strategic Plan.

STRATEGIC DIRECTION 3
ENHANCING THE LEVEL OF IBBS DATA USE

IBBS data comprise an important part of strategic information on HIV/AIDS in Ukraine since they allow to assess the efficiency of the national and regional HIV/AIDS response programs; plan and budget prevention programs and treatment programs among key populations; model the development of HIV epidemic in Ukraine. By the aid of IBBS results, it is possible to establish the actual incidence of HIV infection among key populations (to identify recent cases of infection using rapid tests and DBS testing) and obtain information for the construction of a cascade of treatment for key populations, including timely registration of HIV-positive patients in medical facilities, prescription of ART and effective treatment to achieve undetectable HIV viral load.

IBBS data may be used for designing HIV/AIDS response programs, and to advocate changes, form preconditions for future research, namely:

(1) provide information for the HIV/AIDS response programs on the target group according to its social and demographic characteristics, risk behavior and morbidity;

(2) evaluate the access to prevention and treatment programs for key populations, as well as thier coverage and acceptability;

(3) identify the regions, where key populations require more extensive coverage with prevention programs and access to ART;

(4) evaluate the use of services in terms of providing continuous HIV prevention, treatment and care;

(5) demonstrate the need to increase funding to provide for the expansion of program activities;

(6) highlight issues related to stigma, discrimination and violence.

Objective 3.1. Ensure the effective dissemination of IBBS results

Measure 3.1.1. Creation of a communication strategy for IBBS support with the identification of target groups at the regional, national, and international levels, dissemination of results and their distribution channels.

Measure 3.1.2. Dissemination of IBBS results not only in the context of public health and the role of key populations in the HIV epidemic, but in behavioral practices and social aspects of life of key populations.

Measure 3.1.3. Using the potential of websites and official PHC social network pages in Facebook as well as organizations involved in the relevant research.

Measure 3.1.4. Draw up reports of different types based on research results for the operational provision of IBBS results: technical report on logistic and formative research, analytical report with aggregated indicators on the prevalence of HIV, HCV, risky behavior, etc., and summary report with main results.

Objective 3.2. Optimize the work of the National Strategic Information Portal on the HIV/AIDS response

The need to optimize the work of the Portal is indicated in the "Report on the results of the evaluation of a unified system for monitoring and evaluating the effectiveness of measures aimed at preventing the spread of the HIV epidemic in Ukraine: national and regional levels". This report encloses a recommendation on a creation of a special depositary that could contain protocols, data sets, analytical reports, and other research materials.

Measure 3.2.1. Creation of interactive visualization and dashboards for triangulation analysis on the indicators to reach 90-90-90 targets and effectiveness of HIV prevention.
Measure 3.2.2. Formation of the publication base following the previous IBBS rounds.
Measure 3.2.3. Formation of data repositary of the previous IBBS rounds in Ukraine. The repository will consist of: Protocol and tools, data sets, reports and other materials.
Measure 3.2.4. Providing access to available materials, in particular, to the data bank, for registered users for further monitoring and use of data.

Objective 3.3. Strengthen the use of IBBS data as the evidence base for managerial decisions at the national and regional levels

Measure 4.2.1. Involve pre-identified national and regional level stakeholders in the process of planning and discussing the IBBS results.
Measure 4.2.2. Based on the IBBS results, provide recommendations on the program activities (for example, on the changes of the scope of services within the PLHIV prevention package).
Measure 4.2.3. Make a presentation of research results during the first 3 months after drawing of the final report for the Oblast Coordination Councils on Counteracting TB and HIV/AIDS.
Measure 4.2.4. Conduct trainings for regional specialists on the data analysis and the use of IBBS results.
Measure 4.2.5. Disseminate IBBS results at the international level via presentations, thematic meetings, and conferences, publications in peer-reviewed international journals.
Measure 4.2.6. Ensure that the questionnaire includes the questions, the answers to which will be included in the National Report of Ukraine on the Implementation Progress of Global AIDS Response within the UNAIDS strategy (GAM).

Показн National Report Indicators on the Implementation Progress of Global AIDS Response based on the IBBS Results

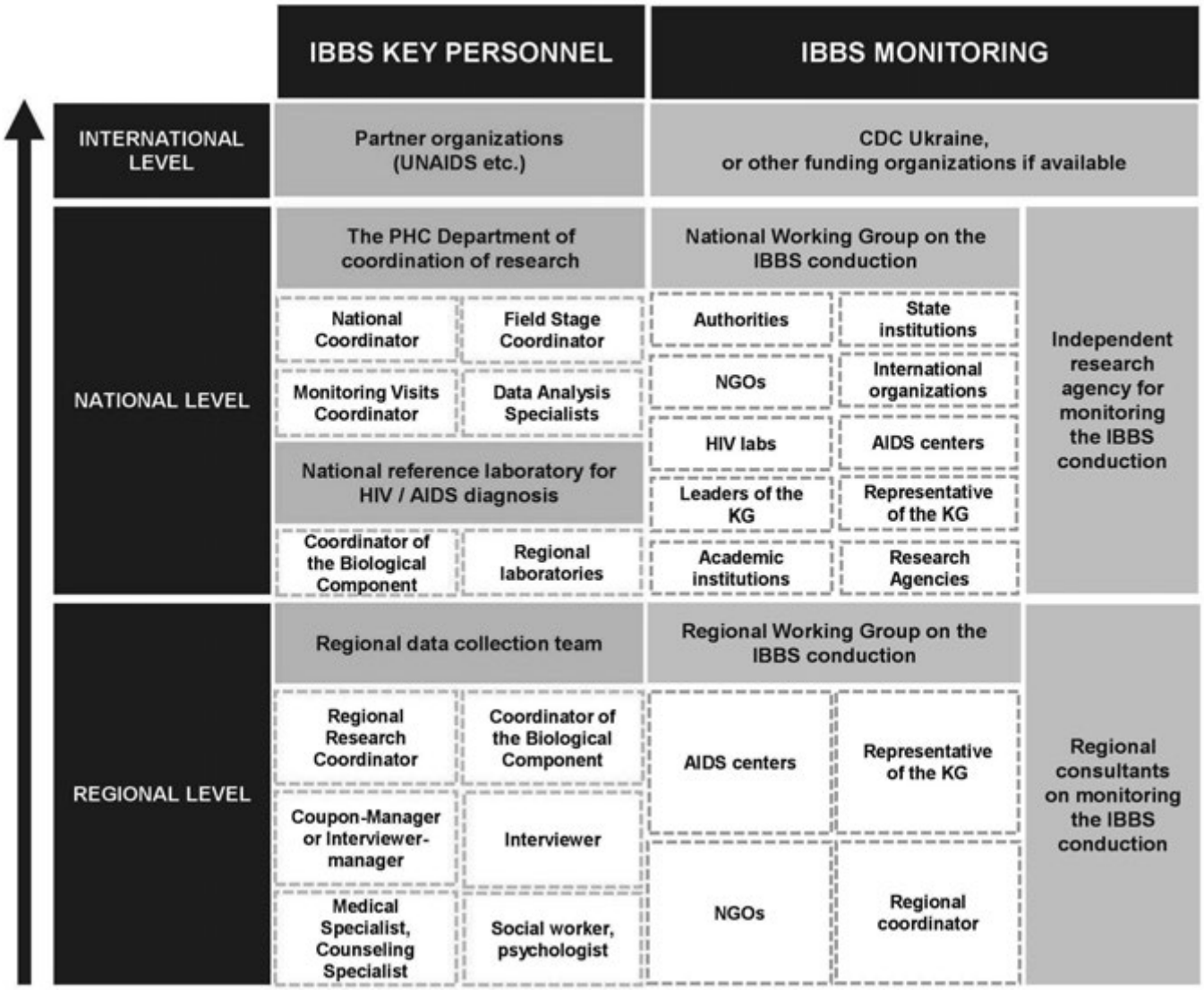
<table>
<tr><th>PWID</th><th>SW</th><th>MSM</th></tr>
<tr><td colspan="3">HIV prevalence; Testing for HIV; PLHIV coverage by antiretroviral therapy; Use of condoms; Coverage by HIV prevention programs; Prevalence of viral hepatitis (HBV and HCV)</td></tr>
<tr><td>Safe injections practice</td><td colspan="2">Prevalence of active syphilis</td></tr>
</table>

STRATEGIC DIRECTION 4

STRENGTHENING THE CAPACITIES OF IBBS PERSONNEL, IN PARTICULARY, ITS PURCHASING POTENTIAL

In 2018-2021, IBBS personnel in Ukraine will be represented by the PHC specialists, the involved consultants, partners and key stakeholders.

A matrix of personnel involved in the conduction of IBBS in 2018-2021



In accordance with the Order of the PHC dated July 19, 2018, No. 38-од, the Ethics Commission was established. The Commission's responsibility will be to examine all IBBS documents as well as support and monitor the research performance, making sure that it is conducted at the best and qualitative level.

Objective 3.1. Formation of IBBS personnel in Ukraine

Measure 3.1.1. Development and strengthening of the analytical and research potential of the PHC department for coordination of scientific research, responsible for IBBS.
Measure 3.1.2. Assessment of partnership on HIV/AIDS at the national and regional levels among state and local authorities, state institutions, non-governmental organizations, international organizations and projects, medical facilities, including HIV laboratories, and medical facilities providing AIDS support, key community leaders, academic institutions, and research organizations.
Measure 3.1.3. Formation of the National Working Group on the implementation of IBBS in Ukraine and ensuring its work throughout the research period.
Measure 3.1.3. Formation of regional IBBS working groups on monitoring the spread of HIV/AIDS (AIDS centers, public health centers), key groups, NGOs working with the target research group, and the regional data collection coordinators.
Measure 3.1.4. Ensuring the work of regional IBBS working groups in Ukraine by holding a minimum of five meetings: at the stage of the formative research; 1 week after the launch of the field stage; 2-3 weeks after the launch of the field stage; after the end of the field stage; after preparation of the final version of the report on IBBS results.
Measure 3.1.5. Formation of regional data collection teams including six main positions: regional research coordinator; biological component coordinator; coupon-manager (RDS) or interviewer-administrator (TLS); interviewer; medical specialist, IT-specialists; social worker/psychologist.
Measure 3.1.6. Formation of regional monitoring consultants team for the IBBS implementation in respective towns.
Measure 3.1.7. Formation of an independent external experts team to monitor the compliance of a research company with IBBS methodology in the regions.
Measure 3.1.8. Strengthening the capacity of the National HIV/AIDS Reference Laboratory and involving its personnel in the IBBS biological component in Ukraine.

The PHC involves the National HIV/AIDS Reference Laboratory and the regional laboratory in Odesa into the process of IBBS conduction in Ukraine. For this purpose, the PHC has created a Laboratory Management Department to coordinate the development of the laboratory network, in particular, the process of reformatting and equipping regional laboratories in Lviv and Kharkiv, which will be involved progressively in the laboratory component of IBBS. Specialists of the National HIV/AIDS Reference Laboratory within IBBS should achieve and maintain a high level of accuracy and professionalism in conducting diagnostic studies, quality control studies, and higher level studies (e.g., drug resistance, genotyping). In addition, laboratory specialists will be visiting IBBS sites to monitor the testing and management control procedures of the IBBS laboratory data in the regions.

Possible changes	Preconditions
Involvement of regional laboratories in Odesa, Lviv, and Kharkiv in laboratory analysis of the future rounds	Expansion of the network of HIV multifunctional laboratories in the regions (Lviv, Kharkiv)
Involvement of the State Institution “Institute of Epidemiology and Infectious Diseases named after L.V. Gromashevsky of the National Academy of Medical Sciences of Ukraine” in Dried Blood Spot (DBS) testing for early detection of HIV infection	Slow pace of development and resource constraints of the National Reference Laboratory at the time of the preparatory phase of IBBS implementation.
Involvement of the National HIV/AIDS Reference Laboratory in all research stages: from design to the distribution of results.	Capacity of the National Reference Laboratory required to meet the needs of all IBBS stages.

Objective 3.2. Quality IBBS personnel training in Ukraine

Measure 3.2.1. Conducting trainings for the national IBBS team on: data visualization, in particular, mapping; methodology and algorithm for assessing the number of key populations; software, RDS-Analyst and SPSS; analysis of data based on RDS and TLS; compliance with the ethical principles for conducting research with human participants, preparation of scientific publications for international journals.

Measure 3.2.2. Conducting trainings for the regional IBBS teams on: methodology and procedures of formative assessment; interviewing and biological component; compliance with SOPs; communication skills with respondents and peculiarities of work with key populations; adherence to safety and professional ethics during research implementation.

Measure 3.2.3. Conducting trainings for health care personnel and non-medical HTS providers within the framework of IBBS with regard to: IBBS procedures; HIV testing in accordance with the National HTS Protocol; adherence to safety and professional ethics during research implementation; and external quality assessment to check the qualifications of specialists in the format of practical classes on collection and analysis of actual biological data.

Measure 3.2.4. Conducting trainings for IBBS monitoring consultants on: IBBS methodology; assessment of compliance by the regional teams with the Research Protocol and SOPs; reporting on the situation on site, in particular, the occurrence of events that may affect the quality of the collected data.

Measure 3.2.5. Conducting trainings for laboratory specialists on: stages of IBBS implementation; laboratory testing within IBBS implementation; analysis and use of IBBS results; quality of research on the determination of serum markers, CD4 cells and HIV viral load.

Measure 3.2.5. Provision of external quality assessment and accreditation of the National HIV/AIDS Reference Laboratory in accordance with the requirements of DSTU EN ISO 15189:2015.

Measure 3.2.6. Conducting trainings or webinars for potential database users, including on the analysis and data use, estimation of the number of representatives of key groups, etc.

All members of the regional team will undergo cross-training within the sociological and biological components in order to ensure the sustainability of the site's operation and continuation of the research in the absence of a specialist in a certain period of time.

3.3. Strengthening procurement potential

For procurement within IBBS, the PHC will use ProZorro, a public procurement platform. As the specificity of conducting tenders through ProZorro is the application of price criterion to a selection of the winning bid, the standard open tender procedure is not suitable for the conduction of procurement within the scope of research. Instead, the PHC will use two others possible ProZorro options:

(1) procurement in case of ultimate necessity, carried out in short terms on the basis of a competitive dialogue and with no restrictions as for the amount of procurement;

(2) specific procurement involving negotiation procedure and setting up different variations of weighting factors for the determination of a winning bid.

Measure 3.3.1. Tendering for the procurement of medical products and consumables for the IBBS biological components through the purchasing of services to provide necessary materials per 1 participant of the target group research.

Measure 3.3.2. Tendering for the procurement of services to coordinate a field stage, organize monitoring visits, conduct independent IBBS monitoring; to design, make a layout and print information materials.

Measure 3.3.3. Tendering for the procurement of tablets for conducting IBBS, survey software.

Measure 3.3.4. Contracting specialists for the development of scripts, maintenance of online questionnaire, IBBS laboratory analysis, IBBS monitoring, data processing and analysis, adjusting the National HIV/AIDS Strategic Information Portal.

Possible changes	Preconditions
The PHC will independently purchase materials for IBBS biological component.	Changes in legislation on procedures for procurement of medical products by government institutions
Materials for IBBS biological component will be procured through intermediaries, e.g., the Alliance for Public Health or the Network.	The impossibility to procure services for providing the necessary materials for IBBS biological component through the ProZorro system.

5 IBBS DATA QUALITY

Simultaneously with the initiated procedure for the institutionalization of the IBBS implementation in Ukraine, one of the priorities for the PHC is to ensure its qualitative conduction.

The mechanism for ensuring IBBS quality in Ukraine

The IBBS planning stage	The protocol and standard operating procedures of the study are coordinated with the National Working Group on the IBBS conduction in Ukraine. Approval of the Protocol and IBBS Toolkit with the PHC Ethics Committee and the Ethics Committee of the financing party (if any). Staff training is carried out on the basis of the IBBS Protocol and SOPs, and their presence and compliance with are checked during monitoring visits on the sites. Carrying out of specialized training for the data collection specialists, namely: regional coordinators, health workers, regional data collection teams, consultants for monitoring the IBBS performance, laboratory specialists.
Field stage	The use of electronic toolkit that lessens the likelihood of errors that might occurs during the data entry, allows automatic tracking of RDS coupons and make compensation payments to the study participants, as well as check recruitment indicators and the quality of the research and biological components of the study. Carrying out monitoring visits to the study sites by the PHC representatives, monitoring consultants, representatives from the side of the financing party, independent research agency, National Working Group on the IBBS conduction. The regional teams report weekly on the data collection progress in the region, in particular, on the recruiting indicators, the number of collected BDS samples, unpredictable and serious adverse events, and response measures. Regional teams forward the information to the PHC on the unforeseen circumstances and serious adverse events no later than 3 days after their detection.
Stage of data processing and analysis	Data management, particularly, at the stages of data processing and analysis, is carried out in accordance with the IBBS data management Plan as part of the Protocol. The analysis is carried out in accordance with the Data Analysis Plan as part of the Protocol. implementation of data management system in the National Reference Laboratory for effective registration, tracking of biomaterial samples and their linkage to the survey data. Quality management of laboratory performance (documenting of procedures and samples, re-testing of a particular fraction of samples) is a key factor to ensuring reliable IBBS results.

Standard Operating Procedures is a set of instructions for conducting the study, which ensure a consistent algorithm on data collection at all IBBS sites.

The approximate structure of SOPs with a step-by-step algorithm for actions concerning specific aspects of the IBBS includes a number of sections, namely:

(1) Greeting of respondents, recruiting and screening;
(2) Obtaining informed consent to participate in the study;
(3) Ensuring the confidentiality of the study participant;
(4) Filling in the study toolkit;
(5) Conducting pre- and post-testing counseling, reporting test results;
(6) Referral to medical facilities and/or prevention programs depending on the test results;
(7) Rapid testing for HIV/AIDS, HCV and other STDs foreseen by the IBBS Protocol;
(8) Preparation, storage and transportation of DBS;
(9) Compensation for respondents and recruitment of secondary respondents;
(10) Study algorithm for participants;
(11) Ensuring security on the survey site for participants and personnel;
(12) Organization of team work on the research site, activation and closure of the site;
(13) Data management on the research site;
(14) Weekly reporting;
(15) Monitoring and quality assurance.

Data management plan is a document that defines the resources and tools needed to collect, store, analyze and use data to effectively plan input, deletion and analysis of data, control the quality of data, manage data usage and exchange, provide continuous management and data documentation. The data management plan covers at least two databases – survey data, laboratory data (RDS coupon management base, if appropriate), which are interconnected through the identification number of a participant.

The document consists of a number of components, namely: data documentation, data dictionary, unique participant's ID, data quality check, skipping pattern, data entry, data privacy, access to data usage, data backup, data archiving and version control, protection and data storage.

Within the Data Management Plan, a "data dictionary" is developed that contains: names and description of variables; possible values for each variable; type of variables; codes for missed values; secondary variables created by code, algorithm or batch file; weights according to a specific variable.

Data analysis plan is a document that includes pre-defined approaches to sample selection, data clearing and transcoding variables, missed strategies, data weighting, HIV prevalence and risk behaviors, spreadsheet format, aggregated values and trend analysis, two-dimensional and multidimensional analysis. The Data Analysis Plan specifies the role and responsibilities of each specialist involved in the data analysis phase, the data analysis schedule and reports/articles publication, the approach to using the previous IBBS data sets and the necessary transcoding of the variables.

General approaches to the IBBS data analysis according to its main objectives

1. ESTIMATE HIV PREVALENCE	When using the RDS method, HIV prevalence is assessed by weighing the data received during the study on HIV prevalence in the representative sample against the size of the respondent's personal social network (in particular: the number of the target group representatives older than 14 years which the respondent has seen in the last 30 days). The indicators obtained at the study regions are aggregated into the overall national HIV prevalence indicator. When using the TLS method, the prevalence of HIV is estimated by weighing, where the arrays of information gathered within each study point act as scales. Namely: the total number of the target group representatives within each study point; the number of people at the study point at the time of the study conduction; the number of people of the target group who participated in the study. Further analysis is carried out using an algorithm similar to RDS.
2. ESTIMATE THE PREVALENCE OF BEHAVIORAL PRACTICES RELATED TO HIV AND THE USE OF PREVENTIVE AND TREATMENT SERVICES	The toolkit contains questions about HIV risk behavior, experience of using alcohol and drugs, features of sexual or drug injecting behavior, and the use of preventive and medical services. Independent variables on these indicators are used to analyze the link with HIV infection. Despite the cross-sectional design of the study, which does not allow to draw conclusions based on casual links, it is still possible to determine the population categories most effected by HIV by using a two-dimensional analysis. Conclusions on the links between independent and dependent variables will be obtained after multi-factor model construction. The determinants of HIV infection are established using multivariate logistic regression analysis.
3. EVALUATE THE HIV MORBIDITY LEVEL	The biological component of IBBS foresees the obtaining of rapid tests results of recent infection and of DBS for viral load detection that will be used to calculate the HIV incidence in each target group. The incidence calculation approaches will take into account the applied sampling approach (RDS or TLS) and will be additionally agreed upon with international experts and statisticians.
4. CALCULATE THE INDICATORS OF THE CASCADE OF SERVICES AND TREATMENT AMONG HIV-POSITIVE PERSONS	The data obtained during the IBBS can be used for the calculation of indicators in accordance with the cascade of services and treatment among HIV-positive persons from the target groups, in particular, to monitor progress towards the achieving UNAIDS goals «90-90-90» to fight the HIV/AIDS epidemic and to identify gaps in existing preventive and treatment programs. The obtained results will also serve as a basis for decision-making on prevention programs among target groups. This is especially important within the framework of the "20-50-80" transition plan according to which the state takes it upon itself to fund HIV/AIDS prevention programs at 80% by 2020 as well as develop their design.
The main characteristics of the target group studies will be stratified by gender, age and other variables. To compare indicators, statistical tests will be used depending on the type of variables and the data distribution (X^2 -test or Fisher test, Student's t-criterion, or Kruskal-Wallis test).	

The IBBS implementation is one of the sources for obtaining data on the number of key populations in Ukraine. The objective of the estimation of the number of KP's:

(1) understanding the potential role of key populaions in the development of the HIV epidemic in Ukraine;

(2) forecasting the HIV/AIDS situation in the country and the scale of epidemic spreading;

(3) assessing the future rating scale of the HIV epidemic in the absence of effective preventive measures;

(4) assessing the coverage of target groups with prevention services;

(5) definining quantitative indicators of the development of prevention programs;

(6) receiving information for planning the development of HIV-services.

To estimate the population numbers, direct (population surveys and "network expansion methods") and indirect, as in a case with Ukraine, methods of assessment are used. The indirect methods of assessment include:

(1) census and enumeration, i.e., the number of people in the target group is determined based on the data of their number on the sites;

(2) the method of capture-recapture is used when there are data of several IBBS rounds. The use of the method involves the inclusion of the question of the respondent's similar experience of the first wave participation, into the toolkit of the second survey wave. Knowing the number of respondents for the first time and their share in the sample of the second "coverage", it is possible to estimate the total number of the target group;

(3) the multiplier method is used for estimatation of the number of representatives in the target group based on the information from at least two independent sources. For example, such sources are the statistical indicator of registered SWs in NGOs and a share of SWs who confirmed their belonging to the group during IBBS implementation. The total number of SWs is based on the volume of this section.

Algorithm of the assessment analysis of the number of key groups in Ukraine

1. ASSESSMENTS CALCULATION AT THE LOCAL LEVEL (AT THE SETTLEMENT LEVEL)	The broadest probable range of the target group size at the study site is determined taking into account the limited minimum (hospitalization statistics to narcological dispensaries) and the limited maximum (index of the settlement population aged 15 to 59 depending on the target group).
2. TRIANGULATION OF THE OBTAINED DATA	The criterion for determining the recommended for use averaged population indicators – a zone of intersection of the maximum number of estimated ranges, and their subsequent approval by the experts. If the obtained indicators differ greatly, the "double perspective" indicator is used additionally, for example, based on the estimated range of the PWID number and the PWID and SWs answers to the questionnaire
3. EXTRAPOLATION OF LOCAL ESTIMATES TO THE OBLAST LEVEL	Use of extrapolation multipliers determined by the National Working Group on the IBBS conduction.

6 ETHICAL PRINCIPLES OF IBBS

The mechanism of ensuring the compliance with the ethical principles of IBBS

IBBS planning stage	The protocol and standard operating procedures of the study are examined by the PHC Ethics Commission and Ethics commission of the finance party (if available), will be agreed upon with the IBBS National Working Group. The Ethics Commission conclusion must comply with: Medical Ethics Regulations of the Ministry of Health of Ukraine No. 218 of 01.11.2002; Regulations and principles of the Declaration of Helsinki, adopted by the World Medical Association General Assembly (1964-2000); Medical Ethics International Code (1983); Council of Europe Convention on Human Rights and Biomedicine (1997); relevant provisions of the WHO and the International Council for Medical Scientific Societies; the laws of Ukraine. The research team completes a training on the ethical standards of survey conduction and receives a relevant certificate. The national team completes a mandatory online course - Human Research - Group 2 Social & Behavioral Research Investigators by the CITI Program or Protecting Human Research Participants by The National Institutes of Health. Regional teams complete a training on the ethical standards within the framework of preparation for data collection. All team members sign a confidentiality agreement, which explains the procedures of handling confidential data and the responsibilities for agreement violation.
Field stage	Those representatives of target group who provided voluntary informed consent and signed the relevant form are allowed to participate in the study. Participants will receive contact information of a Principal Investigator, the PHC Ethics Committee and the representatives of a regional team. Participants will be able to contact any of them on any questions or comments concerning the study, in particular, if participation or inability to participate in the study has caused him/her any harm. The participant's personal information is confidential. The participant receives a unique code, and those who get the HIV-positive result, are asked to leave their personal data for referral/linkage to care. The study premises are selected taking into account the potential risks for participants or research teams (for example, site visitors should not overhear the answers to the questionnaire or test results). The team does not disclose the list/location of sites until the beginning of data collection.
Stage of data processing and analysis	All electronic study data is stored on the protected servers of PHC, and paper-based data – in the locked premises of PHC. Documents and computers will be protected by a password (at least one small letter, one uppercase letter, one digit and one symbol). The main database has at least three backups. Access to data and documents will be available only to the Principal Investigator and co-investigators, and the responsibilities will distributed among staff (primary data and coding, data entry, analysis, report design). During the dissemination of data, the PHC will take into account the minimal harm risk to participants; data on the place of residence will be grouped into larger categories, and variables that can be used for stigmatization will be removed from the public array.

7 FINANCING THE IMPLEMENTATION OF A STRATEGIC PLAN

Prioritization of IBBS financing sources in Ukraine

	Validation	Comments
1. National budget	Subparagraph "Public Health National Program and measures to combat epidemics" - the Law of Ukraine No. 2233-VIII "On Amendments to the Budget Code of Ukraine", which shall come into force on January 1, 2020	Inclusion of a separate budget line "Financing in the field of public heath" into the state Pool of State Program Funds
2. Target program	National Target Social Program to Fight HIV/AIDS in Ukraine for 2019-2023 or the Resolution of the Cabinet of Ministers of Ukraine dated August 18, 2017 No. 560-p "On Approval of the Action Plan to implement the Concept of Development of Public Health System"	The state funding of IBBS is included into the draft of National Target Social Program to Fight HIV/AIDS for 2019–2023 (undergoes discussion at the time of the Strategic Plan development).
3. Scientific research fund	Resolution of the Cabinet of Ministers of Ukraine dated July 4, 2018, No. 528 "On the National Research Fund of Ukraine"	Acquisition of collective or institutional grants in accordance with the Fund objectives, namely: grant support for fundamental research in the field of social sciences.
4. Local budgets	Oblast Target Social Programs on HIV/AIDS Response for 2012-2023 as a component of the National Target Social Program to Fight HIV/AIDS in 2019-2023	Availability of funds due to the expenditures optimization according to the provided budget items and in case of available fund balance at the end of the reporting year.
5. International projects and grant competitions	The base of international technical assistance projects and organizations, that conduct grant competitions in the field of public health	Monitoring and submission of proposals on regular basis for obtaining funds for the conduction of a IBBS round or separate study components.
6. Public-private partnership	Resolution of the Cabinet of Ministers of Ukraine dated November 25, 2016, No. 384 "On the issues of organizing public-private partnership"	Non-governmental organizations, research organizations and other interested parties propose the inclusion of a set of questions into the IBBS questionnaire on a fee basis to cover for the cost of a separate IBBS component.

8 STAGES AND TERMS OF THE STRATEGIC PLAN IMPLEMENTATION

Stages of the Strategic Plan Implementation

2018-2019	**PREPARATORY STAGE** The institutionalization of the IBBS at the national level; the preparation for the IBBS among PWID in 2020; conduction of the part of a study that precedes the field stage. Emphasis on the formation of IBBS personnel and strengthening of PHC capacity. Conduction of IBBS among transgender population through a sub-granting of research organization having experience in relevant research.
2020	**IMPLEMENTATION STAGE** the IBBS implementation is carried out among PWID starting from the field stage up to the presentation of results. The preparation for carrying out the IBBS among MSM and SWs is underway in 2021, with consideration to the previous experience.
2021	**OPTIMIZATION STAGE** The IBBS is implemented among MSM and SWs based on the experience gained during the conduction of IBBS among PWID. The updated actions algorithm and understanding of the weak and strong points of the study realization provide for a faster and more effective result.
2022-2023	**SCALING UP** The PHC is capable of conducting the IBBS by its own in 2022. The IBBS is planned among inmates in 2022 and among PWID and transgender people in 2023.

9 MONITORING AND EVALUATION OF THE STRATEGIC PLAN IMPLEMENTATION

Monitoring and evaluation indicators:

(1) ready product according to a specific activity;

(2) meeting deadlines.

These are key indicators since shifting deadlines of specific activity within IBBS affects the success of the following activities.

Activities, implementation deadlines, responsible parties, expected qualitative and quantitative indicators are detailed in Annex 1. Operational Plan for the implementation of integrated bio-behavioral survey among key populations of the Public Health Center of the Ministry of Health of Ukraine (2018-2021).

10 REFERENCES

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Annex 1.
Operational Plan of the Implementation Integrated Biological & Behavioral Surveillance (IBBS) among Key Populations by the Public Health Center of the Ministry of Health of Ukraine 2018-2021

№	Activity	Participants and Partner	Deliverables	From	To
1	Obtaining materials of IBBS implementation from the Alliance of Public Health	PHC, Alliance	Final versions of databases were received (1 set)	Oct 2018	Oct 2018
2	Systematization of databases and materials of previous IBBS rounds, translation and unification of databases	PHC	Materials of past rounds were systematized; all databases were translated and unified according to one algorithm (1 set)	Oct 2018	Jan 2019
3	Stakeholders analysis with the evaluation for partnership within IBBS	PHC	A map of stakeholders at the national and regional levels was developed; the partnership opportunity and the level of involvement in the IBBS has been determined (1 annex to the Plan)	Oct 2018	Nov 2018
4	Creating a communication strategy for conducting IBBS and disseminating results	PHC	A communication strategy was developed with the definition of types, levels of information, basic messages and communication channels (1 annex to the Plan)	Jan 2019	Mar 2019
5	Conducting IBBS among transgenders	PHC, Contractor	IBSS was organized and conducted; results were obtained (1 report)	Oct 2018	Dec 2019
6	Participation in estimating the key groups number in Ukraine 2018-2019	PHC, Alliance	Statistics data were collected; PHC took part in triangulation and data analysis (1 report)	Oct 2018	Feb 2019
7	Updating the Regulations and forming of the National Working Group regarding IBBS implementation	PHC	The Regulation of the National Working Group regarding IBBS implementation was formed; a list of potential group members was formed; group members have been identified and their participation was agreed (1 document)	Oct 2018	Nov 2018
8	Meetings and consultations with the National Working Group regarding IBBS implementation	PHC, National Working Group	Meetings with the National Working Group regarding IBBS implementation were held; Protocols, tools, SOPs, preliminary and final results of the IBBS were agreed (4 meetings in 2019, incl. 1 - introductory)	Nov 2018	Dec 2021
9	Preliminary estimation of the sample size and determination of geography for incoming round of IBBS	PHC, National Working Group	The sample size and location for IBBS were identified; consultations with experts were held; the draft proposal was submitted for review, corrected and agreed with the National Working Group regarding IBBS implementation (1 document)	Oct 2018 Nov 2019 Apr 2020	Nov 2018 Dec 2019 May 2020
10	Development of IBBS Protocol	PHC	The IBBS protocol was formed according to the Plan; the Protocol was agreed with the National Working Group regarding IBBS implementationn (1 document)	Nov 2018 Dec 2019 May 2020	Jan 2019 Feb 2020 July 2020
11	Development of IBBS tools	PHC	The IBBS tools were developed taking into account the previous rounds and international and national reporting indicators, the results of consultations with experts; the IBBS tools were agreed with the National Working Group regarding IBBS implementation (1 document)	Nov 2018 Dec 2019 May 2020	Jan 2019 Feb 2020 July 2020

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12	Development of the Standard Operating Procedures and accompanying research forms	PHC	The Standard Operating Procedures were developed, incl. the necessary forms for conducting the formative assessment, monitoring of the research field stage; SOPs were agreed with the National Working Group regarding IBBS implementation (1 document)	Nov 2018 Dec 2019 May 2020	Jan 2019 Feb 2020 July 2020
13	Development of the Protocol for estimating the key groups number in Ukraine	PHC	The IBBS protocol was formed according to the Plan; the Protocol was agreed with the National Working Group regarding IBBS implementation (1 document)	Feb 2019 Feb 2020 July 2020	July 2019 Mar 2020 Aug 2020
14	Conducting a training on data visualization eg mapping of results	PHC, Partners	Facilitators were selected; training materials and list of participants at the national and regional levels were formed; trainings were conducted for more than 50 participants (2 trainings)	Jan 2019	Mar 2019
15	Conducting a training on estimating the key groups number for PHC specialists and national partners	PHC, CDC	Facilitators were selected; training materials and list of participants at the national level were formed; training was conducted for more than 25 participants (1 training)	June 2020	July 2020
16	Conducting a training on using the R for PHC specialists and national partners	PHC, CDC	Facilitators were selected; training materials and list of participantss at the national level were formed; training was conducted for more than 25 participants (1 training)	Jan 2020	Feb 2020
17	Conducting a training on using the SPSS and analyzing TLS for PHC specialists and national partners	PHC, CDC	Facilitators were selected; training materials and list of participants at the national level were formed; training was conducted for more than 25 participants (1 training)	Nov 2019	Feb 2020
18	Conducting a training on using the RDS Analyst for PHC specialists and national partners	PHC, CDC	Facilitators were selected; training materials and list of participants at the national level were formed; training was conducted for more than 25 participants (1 training)	Mar 2020	Apr 2020
19	Conduct training on principles of research ethics for PHC specialists and national partners	PHC, CDC	Facilitators were selected; training materials and list of participants at the national level were formed; training was conducted for more than 25 participants (1 training)	Feb 2019	Mar 2019
20	Translation of the IBBS Protocol and tools, approval from CDC	PHC, CDC	The IBBS Protocol and tools were translated into English; documents were approved by CDC (2 documents)	Feb 2019 Feb 2020 July 2020	Apr 2019 Apr 2020 Sept 2020
21	Approval of the IBBS Protocol and tools in the Institutional review boards of the CDC and the PHC	PHC, IRB	An ethical review of the IBBS Protocol and tools was approved a package of documents was prepared for review; the approval of IRB was obtained (1 document)	Feb 2019 Feb 2020 July 2020	Apr 2019 Apr 2020 Sept 2020
22	Conducting external quality assessment of the National Reference-Diagnostic Laboratory for HIV/AIDS	PHC	An external quality assessment was carried out at the National Reference-Diagnostic Laboratory for HIV/AIDS; recommendations were given to optimize the functioning of the National Reference-Diagnostic Laboratory for HIV/AIDS (1 report)	July 2019	Aug 2019
23	Development and approval of the IBBS budget to secure funding	PHC	IBBS budgets were established with the National Working Group regarding IBBS implementation and relevant PHC specialists (3 budgets)	Jan 2019 Feb 2020 Aug 2020	Feb 2019 Mar 2020 Oct 2020
24	Identify potential funding and grant opportunities	PHC	The grantmakers map was created and priority organizations were identified to monitor grant proposals; grant proposals were monitored during the Plan implementation (1 application per year)	Jan 2019	Dec 2021

№	Activity	Participants and Partner	Deliverables	From	To
25	Preparation of tender documentation and procurement of field coordination services	PHC	Document set was developed for tender procurement; the winner of the tender was selected according to the PHC procedures (1 completed tender)	Mar 2019 Mar 2020 Oct 2020	Apr 2019 Apr 2020 Dec 2020
26	Preparation of tender documentation and procurement of services for conducting trainings and organizing monitoring visits	PHC	Document sets were developed for tender procurement; the winners of the tenders were selected according to the PHC procedures (2 completed tenders)	Mar 2019 Mar 2020 Oct 2020	Apr 2019 Apr 2020 Dec 2020
27	Preparation of tender documentation and procurement of supplies and test systems for the bio-component of IBBS	PHC	Document set was developed for tender procurement; the winner of the tender was selected according to the PHC procedures (1 completed tender)	Apr 2019 Apr 2020 Oct 2020	Sept 2019 Sept 2020 Feb 2021
28	Preparation of tender documentation and procurement of tablets for IBBS implementation	PHC	Document set was developed for tender procurement; the winner of the tender was selected according to the PHC procedures (1 completed tender)	May 2019	Aug 2019
29	Preparation of tender documentation and procurement of survey software	PHC	Document set was developed for tender procurement; the winner of the tender was selected according to the PHC procedures (1 completed tender)	May 2019 May 2020	Aug 2019 Aug 2020
30	Contracting a consultant for creating scripts, setting up and running an online forms incl. questionnaire	PHC	A package of documents was developed for contracting; a consultant was selected according to the PHC procedures (1 completed procedure)	July 2019 July 2020 Dec 2020	Sept 2019 Sept 2020 Feb 2021
31	Formation regional working groups and selection of regional coordinators	PHC, National Working Group	A list of potential group members was formed; group members were identified and their participation was agreed upon; a package of documents was developed for contracting; a consultant was selected according to the PHC procedures (1 completed procedure)	June 2019 June 2020 Nov 2020	Sept 2019 Sept 2020 Feb 2021
32	Contracting specialists in the laboratory analysis of IBBS data	PHC	A package of documents was developed for contracting; a consultant was selected according to the PHC procedures (1 completed procedure)	July 2019 July 2020 Dec 2020	Sept 2019 Sept 2020 Feb 2021
33	Contracting consultants for the monitoring visits within the field stage IBBS	PHC	A package of documents was developed for contracting; a consultant was selected according to the PHC procedures (1 completed procedure)	June 2019 June 2020 Nov 2020	Sept 2019 Sept 2020 Feb 2021
34	Development of tender documentation and procurement of services for conducting independent monitoring during the field	PHC	Document set was developed for tender procurement; the winner of the tender was selected according to the PHC procedures (1 completed tender)	June 2019 June 2020 Nov 2020	Sept 2019 Sept 2020 Feb 2021
35	Meetings with the Regional Working Groups regarding IBBS implementation	PHC, Regional Working Groups	A meeting with the national IBBS team with the Regional Working Groups regarding IBBS implementation was organized and held (at least 1 meeting)	Sept 2019 Sept 2020 Feb 2021	Nov 2019 Nov 2020 Apr 2021
36	Reproduction accompanying materials of IBBS for the Regional Working Groups regarding IBBS implementation	PHC	A set of accompanying research materials was prepared for the IBPS; printing and transfer of materials to regional teams were provided (1 set of documents for each regional team)	Sept 2019 Sept 2020 Feb 2021	Nov 2019 Nov 2020 Apr 2021
37	Meetings of the Regional Working Groups regarding IBBS implementation	PHC, Regional Working Groups	A meeting schedule of the Regional Working Groups regarding IBBS implementation was drawn up and agreed; monitoring of meetings was provided (at least 4 meetings per 1 round, 4 reports)	July 2019	Dec 2021
38	Preparation of materials, organization and conduct of training for regional coordinators	PHC, Contractor	Facilitators were selected; training materials and list of participants were formed; at least one regional specialist have participated in the training (1 training)	Oct 2019 Nov 2020 Apr 2021	Dec 2019 Jan 2021 June 2021

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39	Preparation of materials, organization and conduct of training for regional teams	PHC, Contractor	Facilitators were selected; training materials and list of participants were formed; at least six regional specialists have participated in the training (1 training)	Oct 2019 Nov 2020 Apr 2021	Dec 2019 Jan 2021 June 2021
40	Preparation of materials, organization and conduct of training for medical officers	PHC, Contractor	Facilitators were selected; training materials and list of participants were formed; at least one regional specialist have participated in the training (1 training)	Oct 2019 Nov 2020 Apr 2021	Dec 2019 Jan 2021 June 2021
41	Preparation of materials, organization and conduct of training for laboratory specialists	PHC, Contractor	Facilitators were selected; training materials and list of participants were formed; at least one regional specialist have participated in the training (1 training)	Oct 2019 Nov 2020 Apr 2021	Dec 2019 Jan 2021 June 2021
42	Preparation of materials, organization and conduct of training for consultants of monitoring visits	PHC, Contractor	Facilitators were selected; training materials and list of participants were formed; at least one regional specialist have participated in the training (1 training)	Oct 2019 Nov 2020 Apr 2021	Dec 2019 Jan 2021 June 2021
43	Conducting formative assessment in the regions incl. data validations	PHC, Regional Working Groups	The formative assessment was organized and conducted in the region; key informants, primary seeds, research sites were selected; the mapping and data validation were carried out (1 report from the region)	Jan 2020 Jan 2021 June 2021	Feb 2020 Feb 2021 Aug 2021
44	Discussing results of formative assessment and approval of the field stage of IBS	PHC	Meetings with the National and Regional Working Groups were organized and held; a roadmap of the field stage was created, incl. schedule of work sites, etc. (1 document)	Feb 2020 Feb 2021 Aug 2021	Feb 2020 Feb 2021 Aug 2021
45	Preparation of research sites, search for premises and their equipment	PHC, Regional Working Groups	The monitoring and selection of premises/vehicles for the conduct of IBBS were carried out; work stations for team members were equipped (1 technical report from the region)	Feb 2020 Feb 2021 Aug 2021	Feb 2020 Feb 2021 Aug 2021
46	Conducting the field stage of IBBS, collecting the behavioural and biological data	PHC, Contractor	Recruiting, screening, the collection of behavioral data and biological samples, data transfer to the national team according to SOP were provided; data were collected according to the established sample sizes (1 technical report from the region)	Mar 2020 Mar 2021 Sept 2021	July 2020 July 2021 Dec 2021
47	Daily monitoring and support for regional teams required, in order to comply with the quality of data collection.	PHC, Contractor	Daily communication with regional teams was carried out during data collection; feedback was provided if necessary (1 technical report from the region)	Mar 2020 Mar 2021 Sept 2021	July 2020 July 2021 Dec 2021
48	Implementation of monitoring visits to research sites	PHC, CDC, National Working Group, Contractor	Monitoring visits to data collection sites were carried out by specialists of PHC, donors, the National Working Group, independent monitoring consultants and an independent research agency; reports on the results of monitoring visits were received; feedback was provided on the quality of the field stage	Mar 2020 Mar 2021 Sept 2021	July 2020 July 2021 Dec 2021
49	Holding operational meetings to discuss the results of monitoring visits	PHC, National Working Group, Regional Working	Operational meetings of the PHC team, donors, and the National Working Group were organized according to the results of monitoring visits (if necessary, at least 1 meeting)	Mar 2020 Mar 2021 Sept 2021	July 2020 July 2021 Dec 2021
50	Discussion of the results of the field stage of IBBS	PHC, National Working Group, Regional Working Groups	Meetings with the National and Regional working groups on the results of the field stage were organized and held; the specific regional contextual details for the implementation of the field stage in each region was obtained (1 meeting in the region with 1 technical report)	Apr 2020 Apr 2021 Oct 2021	July 2020 July 2021 Dec 2021

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51	Cleaning and validation of IBBS database	PHC	IBBS data were cleaned and logical controled (1 database)	Mar 2020 Mar 2021 Sept 2021	July 2020 July 2021 Dec 2021
52	Processing survey and testing data	PHC, Contractor	Behavioral and biological data were processed; the quality of the data and possible deviations from the IBBS algorithm were identified according to the IBBS Protocol (2 databases)	Apr 2020 Apr 2021 Oct 2021	Nov 2020 Nov 2021 Dec 2021
53	Statistical analysis of behavioral data	PHC, Contractor	IBBS data were analyzed according to the Analysis Plan and the IBSS Protocol (1 preliminary report-summary)	June 2020 June 2021 Dec 2021	Oct 2020 Oct 2021 Dec 2021
54	Laboratory analysis of biomaterials	PHC, Contractor	Data of rapid tests and samples of a dry drop of blood for a recent infection and viral load were analyzed (1 database)	June 2020 June 2021 Dec 2021	Oct 2020 Oct 2021 Dec 2021
55	Formation of the final IBBS database	PHC, Contractor	Behavioral and biological analyses were combined and compared: obtained database was updated with the technical data/details (1 database)	Oct 2020 Oct 2021	Dec 2020 Dec 2021
56	Creating the technical, analytical and summary reports on the IBBS results	PHC, Contractor	The structure and content of the technical, analytical and summary reports on the IBBS results were determined; relevant documents were written and drawn up after consultation with the National Working Group (3 final reports)	Sept 2020 Sept 2021	Feb 2021 Dec 2021
57	Conducting training on preparation of the scientific articles for international publications for PHC specialists and national partners	PHC, CDC	Facilitators were selected; training materials and list of participants at the national level were formed; training was conducted for more than 25 participants (1 training)	Apr 2020 June 2021	June 2020 Aug 2021
58	Contracting IT-specialist for correction of the IBBS section on the National Strategic Information Portal	PHC, Partners	A package of documents was developed for contracting; a consultant was selected according to the PHC procedures (1 completed procedure)	TBD	TBD
59	Correction of the National Strategic Information Portal and creation of the IBBS presentation page	PHC, Partners	The necessary changes were identified and agreed with the Plan for using of strategic information, M&E system and the needs of stakeholders; working meetings with stakeholders were held; the task description for updating the Portal was formed (1 updated resource)	TBD	TBD
60	Update the National Strategic Information Portal	PHC, Partners	IBBS materials were systematized; levels of IBBS data access were determined and posted on the Portal (1 resource section)	TBD	TBD
61	Estimating the target group number in Ukraine	PHC, National Working Group, Regional Working Groups	Statistics data were collected; approval and processing of the data were provided; preliminary estimated ranges were calculated; the findings were agreed with the National and Regional Working Groups; the final key groups number were established (1 report)	Dec 2020 Nov 2021	Mar 2021 Dec 2021
62	Preparation of tender documentation and procurement of design services, layout and reproduction of information materials of IBBS	PHC, Contractor	Document set was developed for contracting; a consultant was selected according to the PHC procedures (1 completed procedure)	Nov 2020 Oct 2021	Mar 2021 Dec 2021

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63	Creating information materials on the IBBS results	PHC, Contractor	Design and layout of materials were carried out according to the communication strategy (1 set of information materials)	Jan 2021 Dec 2021	Mar 2021 Dec 2021
64	Presentations of research results and hold meetings particularly regional level	PHC, Regional Working Groups	A meeting schedule with results presentation at the national and regional level was prepared; the list of participants and meeting materials were compiled (at least 3 meetings at the national level and 1 meeting in the regions)	Oct 2020 Sept 2021	Mar 2021 Dec 2021
65	Conducting trainings / webinars on the analysis and using IBBS data and results of estimating the key groups number in Ukraine	PHC, National Working Group	Facilitators were selected; training materials and list of participants at the regional level were formed; training / webinar was conducted for more than 25 participants (1 training/webinar)	Mar 2021	Apr 2021
66	Dissemination of data and results of IBBS according to the communication strategy	PHC	IBBS data dissemination was ensured and implemented according to corresponding levels, types and channels of communication; feedback was established with recipients/users of information; data use was monitored on an ongoing basis (1 document)	Mar 2021	Dec 2021

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