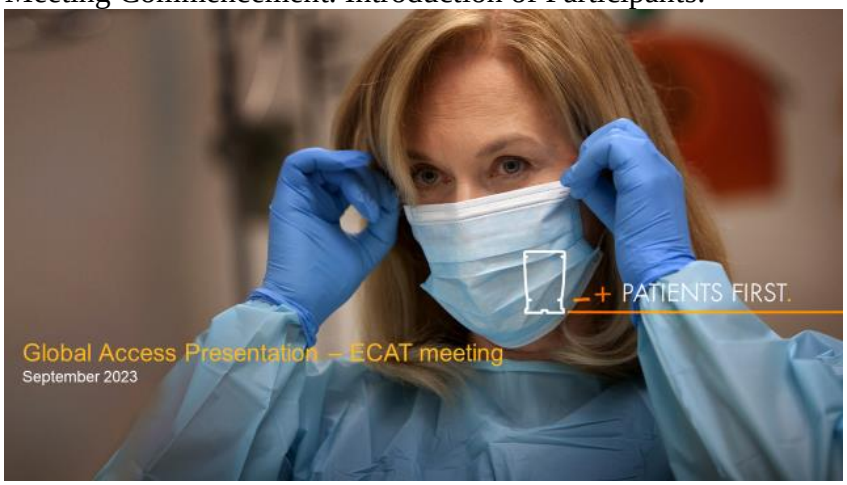
Meeting Protocol of the "Eurasian Community for Access to Treatment" with "Cepheid" Company

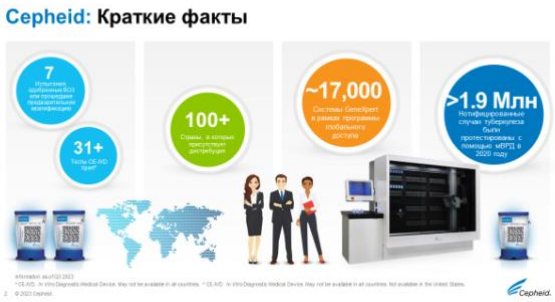
September 28, 2023

Organization Representatives:
Nduku Ndunda – Director Global Access Virology Solutions
Alexey Lustin – Service Manager for the CIS and Turkey Region

Meeting Commencement. Introduction of Participants.

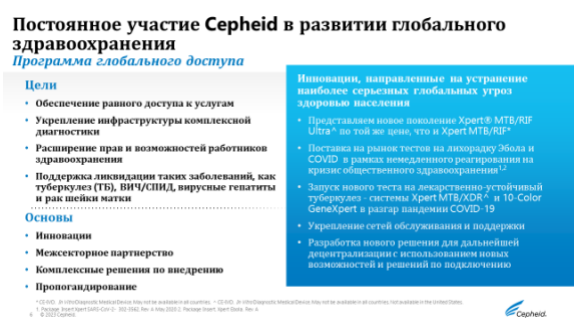


Cepheid's extensive portfolio encompasses over 31 tests on the GeneXpert platform, including seven WHO-prequalified tests, serving markets in over 100 countries. Through our Global Access Program, we've deployed 17,000 systems, conducting over 1.9 million tuberculosis tests in 2020 alone. With 19 offices globally, including manufacturing facilities in the United States, Sweden, and India, and 76 ASP in 92 countries



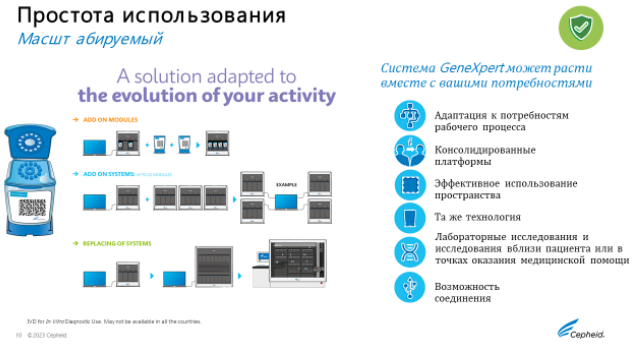
Our global fleet of over 73,000 modules, is able to run a wide range of our tests as highlighted in the slide below. The MTB/RIF Ultra test is registered in more than 100 countries globally.

Our mission is to deliver a better way to improve patient outcomes by enabling access to molecular diagnostic testing everywhere. Cepheid's Global Access Program centers on the belief that everyone, everywhere should have access to high quality diagnostic tests. That's why for more than a decade, we have worked to improve healthcare outcomes through expanded access to reliable and fast molecular diagnostic testing solutions— especially for critical medical conditions like HIV, tuberculosis and our pandemic prepared solutions Covid-19 and Ebola.



Cepheid engages directly with donors, policymakers, governments, NGOs, communities, and patients to ensure our work supports global, national, and local health system and disease elimination goals in low- and middle-income countries. Some of the organizations across the 136 countries (Shown in the map below), that we collaborate with under the Global Access program include Médecins Sans Frontières (Doctors Without Borders), OXFAM, and the International Red Cross among others, as well as international financing mechanisms such as the Global Fund, STOP-TB, UNITAID, PEPFAR, and USAID. Private -public partnerships are also eligible on a case-by-case basis.

The GeneXpert System is available in a 2, 4,16, 48, or 80-module configuration that is able to adapt to the evolve to fit your labs activities.
Our principle is to enable equipment adaptation to any laboratory size and needs. The GeneXpert four module is the most common systems. Modules can be added as demand increases, as illustrated below.



The consistent operating principle makes it easier to train specialists. Our primary goal is to provide patient-centric diagnostics. To prevent patient loss, we emphasize the "test and treat" approach.
On September 19, 2023, Cepheid announced that it will be providing Xpert® MTB/RIF Ultra* at cost and will earn no profit on this test. The Xpert® MTB/XDR test was also reduced by 25%, from $19.8 to $14.9 USD earlier in 2023.[1] Cepheid has remained committed to driving for more accessible pricing for programs and patients for the last few decades and has also rolled out an all –inclusive offering for Xpert HIV Qual XC , Xpert HIV VL, Xpert HCV, Xpert HBV, Xpert HPV tests. This offer comes with a free GX-16 system, with a commitment to supply 10,000 tests per year for a duration of 3 years. The cost covers the systems and their maintenance.

Soon, Cepheid will be rolling out the hybrid software which will allow 6 color systems to have 10 color modules installed on the same system. This is particularly relevant to Eastern Europe and Central Asia, where there is a high prevalence of or drug-resistant tuberculosis.

We offer various service and support options from the time of shipment for GeneXpert systems that are either already installed in laboratories or planned for purchase. Under the Global Access program, all equipment is shipped with a default two-year warranty..

Question: Is calibration the insertion of the Xpert Check cartridge or something else? Is this procedure carried out directly in the laboratory?

Answer: The procedure is performed on-site in the laboratory. The Xpert Check kit is used to check the functionality of each module. A special report is generated based on the results, and we assess the condition of the equipment.

[1] https://investors.danaher.com/2023-09-19-Danaher-to-Provide-Cepheids-Tuberculosis-Test-to-the-Global-Fund-at-Cost

After the warranty period, we can offer various options. First, you can opt out of guaranteed service and contact us on a case-by-case basis if something happens to the equipment, including reaching out to our service partners in certain countries. We can also offer service contract options called "extended warranty" and "extended warranty plus," as well as the Access Care program. The slide below indicates that 90% of systems can be serviced by our authorized service provider (ASP). This refers to the entire coverage area of the program, not just the EMEA region.

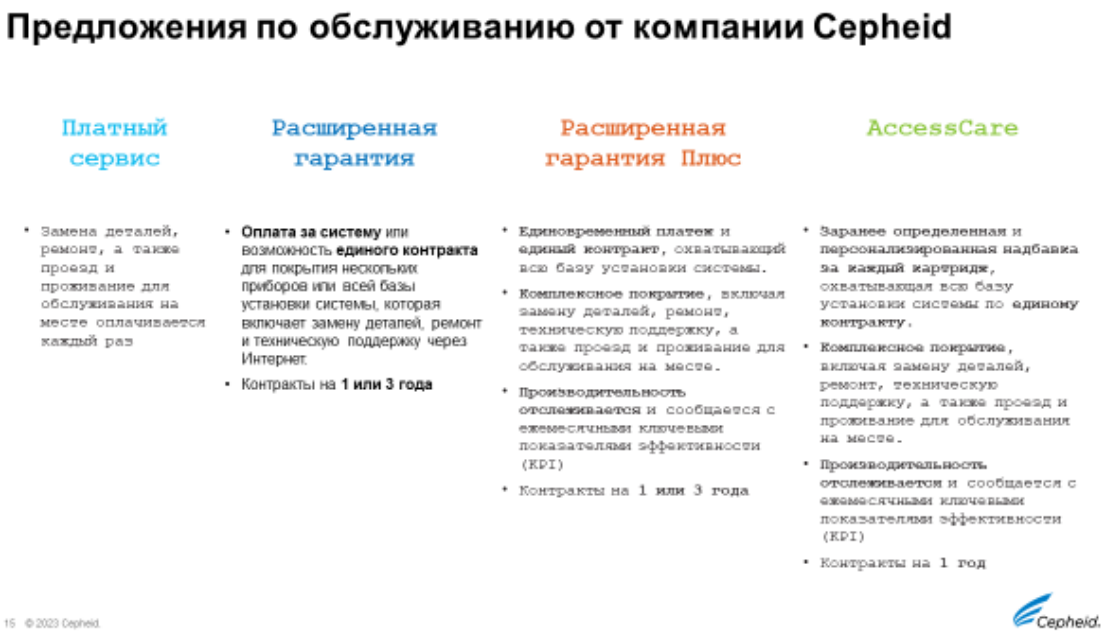
If you are working with us under commercial service terms and an event occurs with the equipment, such as the need for part replacement, diagnostics, or updates, you can reach out to a service partner or us, and all services will be provided on a fee basis. We supply spare parts and more.

Extended warranty is essentially a service contract. Under the extended warranty, you receive the same services as from the moment of purchasing the device. All spare parts are provided free of charge, and technical support is also provided free of charge. Currently, there are options to extend service contracts for one or three years. These can be purchased either at the time of equipment purchase, which is more cost-effective, or at any time during equipment use. It's crucial to note that service contracts include an Xpert Check kit, allowing for annual equipment maintenance and functionality checks.

The extended warranty Plus includes comprehensive coverage in addition to the previous contract. This comprehensive coverage includes travel and accommodation expenses for a specialist to reach the location of the equipment and perform all necessary actions to restore its functionality. Contracts are available for one or three years on the same terms. We offer the option to contract for all systems at once, unlike the previous option where you can purchase a warranty for each system individually. Additionally, Cepheid commits to providing reporting on specific KPIs regarding the speed and quality of servicing your equipment.

The Access Care program is similar to the extended warranty Plus program but uses a slightly different algorithm. We offer a personalized surcharge to the cartridge cost, calculated individually from country to country and program to program. It is a unified contract covering the entire system as it is a reagent contract. The contract provides comprehensive coverage with an "all-inclusive" approach, including expenses for parts delivery, customs clearance, the arrival of service specialists, and more. The only limitation is that such contracts are only

concluded for one year.



Question: In the paid service, Xpert Check is not included. Does this mean that it needs to be paid for separately?

Answer: Under the commercial service, any operations with the equipment will be paid, including annual maintenance, which includes Xpert Check. Under the special pricing program, Xpert Check will also be offered at a special price significantly lower than the commercial price. Planning and procurement of equipment in advance will be necessary.

Question: Can you provide prices under these programs? Are they standardized across all coverage zones?

Answer: The High-Burden Developing Country (HBDC[2]) program is standardized for all countries that meet its criteria. This program has standardized prices not only for cartridges, tests, and systems but also for service maintenance and spare parts. These prices have been published on the Global Fund website and presented in catalogs by USAID and other donors.

Question: Do we understand correctly that a one-year contract under the AccessCare program implies only one year of favorable terms, after which service transitions to a commercial basis?

Answer: The contract is valid for one year. During this year, we fulfill the obligations necessary for servicing the equipment. After a year, we revisit the question of whether to extend this contract on the same terms. For example, if cartridge consumption increases in a country, we reduce the delta on cartridges. We review prices, make a new proposal, and if the customer agrees, the contract is extended. If there is a need to switch to another program, we adapt to the customer's needs.,

Question: If, for example, the Global Fund purchases a machine, and the first year is conducted under the AccessCare program, can the machine be further used and transitioned to another program?

[2] http://cepheid.mediaroom.com/2021-05-06-Cepheid-Announces-Updated-HBDC-Pricing

Answer: We do not have the right to insist; the decision is made by the country itself. We only propose various solutions and demonstrate their economic feasibility from different perspectives.

Question: Is training for specialists on-site, workshops, and master classes included in the "Extended Warranty Plus" package, or is it a separate option?

Answer: This program pertains to service maintenance, i.e., interventions to restore the equipment's functionality. Training specialists to work with the equipment, as well as methodological support for working with various tests, is not included in this program. If during the purchase of systems, we see the need for training, this service can be included. This is done in other programs under different conditions.

Question: What is the company's policy on technical maintenance? Do you handle it exclusively, or is there a possibility of involving third-party organizations to make the equipment and its use more accessible?

Answer: From a service perspective, we have a slightly different approach. We will adhere to the terms of equipment sales and the conditions of the program under which we provide the equipment. When purchasing any equipment, the customer agrees to these conditions. They clearly state that servicing or repairing the system must be carried out either by Cepheid specialists or certified specialists approved by Cepheid. In extreme cases, maintenance and repair may be carried out on-site with Cepheid's approval. This is not done to earn money on servicing but because this IVD medical equipment produces results based on which specific treatments are prescribed. Accordingly, Cepheid is responsible for the results issued, and we do not completely shift the responsibility to the laboratory. That's why we are so meticulous about who and how services the equipment we supply to the markets.

If Cepheid lacks resources for servicing in a particular region due to demand or installation base, we engage service companies that we train and certify, and we periodically conduct audits. We also inform end-users that there is a service company in a specific region that can provide equipment maintenance and technical support.

In some regions where, for various reasons, we cannot engage service partners and cannot work directly ourselves, we either instruct laboratory staff or train local personnel. These are so-called training sessions for super-users.

Question: Are we correct in understanding that the certification program applies to companies, not individuals? What is your policy regarding companies? Should they work exclusively with you, or is it possible for the same company to, for example, service both GeneXpert and Truenat?

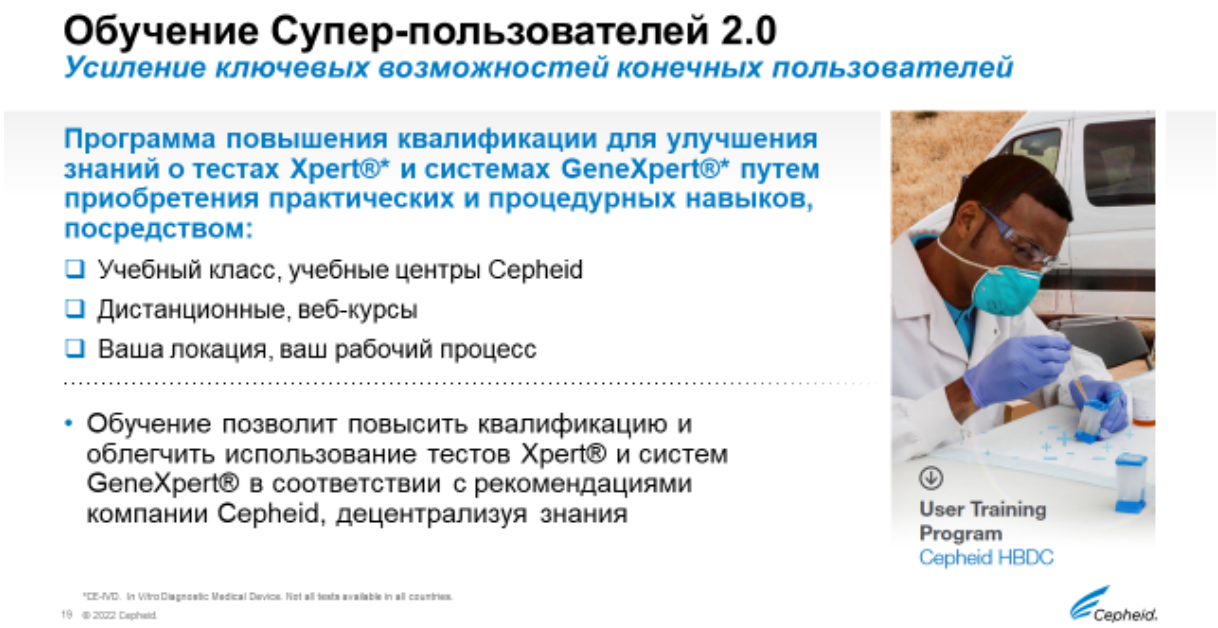
Answer: We issue a certificate and certify an individual specialist. However, their certificate will be valid only as long as they work in the organization for which we provided the training, or until the certificate expires. We are moving away from the practice of certifying only service companies and returning to the practice of training super-users[3] for the region.

One of the recent training sessions took place in July of this year at our training center in Dubai. We trained 14 different specialists from five countries in the region, and all of them received

[3] https://stoptb.org/assets/documents/events/meetings/5.Cepheid_%20Stakeholders%20Meeting%20Paris%20Oct28%202013.pdf, c. 19

certificates. As long as they work in healthcare organizations, they can perform equipment maintenance, including training specialists on-site without issuing certificates, but with skills in operating the equipment. We are launching such programs more and more often. We announce them either through non-profit organizations in the region, through the Ministry of Health, or through end-users.

The last time, we received a very large number of applications and could not approve everyone immediately. We plan to repeat the training cycle soon, possibly at the end of this year or the beginning of the next. This program has had a significant impact not only in the MENA region but also in Africa and Asia. The program is gaining popularity as a complement to our service offerings in the market.



Here are the results of the evaluation of our activities in countries where the AccessCare program has been implemented. All systems were supervised by service specialists because the contract implies comprehensive coverage for all systems. We were able to increase the utilization of modules from 80–90% to almost 100%. In other words, in the region of presence, only individual modules remained non-functional. Thus, we have increased throughput. Preventive maintenance, including the replacement of parts, should be done in a

timely manner to anticipate possible breakdowns.

The AccessCare program includes Cepheid's C360 software, which allows remote monitoring of equipment status, systematic processing of test results, and the generation of statistical data, including the percentage of positive, negative, and indeterminate test results. This program is constantly being modified, with new features being added. In the future, we plan to expand the functionality, for example, by adding the ability to proactively order reagents.

As of today, out of the 11 countries where the HBDC program has been implemented, there are authorized service companies in 4 countries that undergo periodic audits. They are represented on the slide below. If more detailed contacts are needed, we can provide them. Within the HBDC program, you can seek on-site support. These authorized service companies are available in your time zone, speak your language, and are ready to provide service support

quickly.

Question: Has the number of authorized service partners decreased in individual countries over the past two years due to sanctions or other factors?

Answer: No, there has been no reduction in the number of service partners due to sanctions. The number of service partners may change from year to year based on various factors. For example, in Kazakhstan, we initially had two service partners. At some point, we decided that one partner was sufficient to meet the country's needs. Additionally, when evaluating a service company, we make a decision each time about whether to renew the contract. This decision is not solely ours – we gather feedback from end-users, inquire about the need for additional support in the country, and consult with health ministries. If they are capable of handling things on their own, we support that. At the same time, we attract new companies where expansion is deemed necessary.

Question: Are we correct in understanding that in Ukraine, there is one individual entrepreneur, Mr. Skripov, who is also a service center?

Answer: An individual entrepreneur is a form of organization. We don't mind what form the organization takes. As far as we know, he is not the only one and has never been alone. We have certificates confirming the training completion of his colleagues.

Question: The slide mentions "others." What does this mean? For example, if a device in Kyrgyzstan malfunctions, can someone from Kazakhstan come and repair the equipment?

Answer: Yes, it is possible. It is crucial to consider under which contract the equipment is with the end-user. If it is a paid service, all expenses for the specialist from Kazakhstan to travel to the endpoint will be borne by the end-user.

Comment from a representative of the patient community: It seems practical to have one service center in a country, but from the perspective of costs, speed, and quality of service, it's better to have a choice. A monopoly at the country level can negatively impact accessibility. We have heard of cases where equipment remained idle because the organization could not afford repairs due to high costs. We know of one such case, but we are confident that this is not an isolated incident. In this regard, we request a possible reconsideration of the policy and

encouragement of competition between service centers to improve service quality and reduce prices. This would be beneficial for end-users and your company, contributing to increased satisfaction with your products.
Response: Thank you for bringing this up. Which country were you referring to?

Comment from a representative of the patient community: It was in the Asian region, and we cannot specify the country at the moment. As far as we've heard, there have been instances of equipment downtime for several weeks or months in other countries in the region.

Response: We can assume that such situations occur periodically in countries where, under the HBDC program, access to diagnostics is provided, and we supply equipment, service, and parts at significantly lower prices than the commercial market. We primarily work with state clinics that have a budget but no in-house service. Service is often forgotten in the budget for the current year and is excluded from planning. Therefore, such situations mainly occur where the equipment's warranty period has expired, there is no service contract, and the service budget was not planned. Then questions arise about where to find the money. Requests are sent to the Ministry of Health, and if there is no budget, appeals are made to donors. Unfortunately, this process takes time. Cepheid cannot influence this process. Every year, at least once a year, we approach the Ministry of Health, non-profit organizations, our partners, donors, and explain that service must be planned in advance, offering various programs. Each year we update these programs, organize the presence of service partners in countries. In Kazakhstan, we held a competition among service partners; for some time, they worked together, and competition could be assessed. We evaluated primarily from a quality standpoint. At that time, we agreed that the price for end-users from service partners cannot differ and must be affordable for everyone. This limit was specified and agreed at the Ministry of Health level, and no one exceeded it. Service maintenance was and remains accessible.

Question: Tell us about your current plans in Russia, considering the sanctions risks.

Response: Currently, in Russia, we are represented by commercial business with various distributors. Sanction restrictions have certainly affected delivery times to end-users. However, Cepheid's goal is access to diagnostics, primarily a humanitarian goal. Therefore, in accordance with the sanction restrictions imposed on countries, not only Russia, we fulfill our mission and do everything possible within the legal framework.

Question: The community of people affected by tuberculosis reports issues with conducting accelerated tuberculosis testing using the GeneXpert analyzer. What is your company doing for timely deliveries to Kazakhstan? Should we expect diagnostic disruptions in 2024? What can be done to prevent them?

Answer: There were supply disruptions last year, which were related to the fact that the order was not placed according to the country's planning deadlines. As a result, there was a slight interruption. We addressed this situation with the Ministry of Health, the national program, and the Global Fund, and we have stocked up on tuberculosis tests for the next year. We are aware of the test consumption volume in the country, and the next order will be placed in advance to avoid such delays. The disruptions were related to planning, not production. As of today, all shipments for the next year are completed. Kazakhstan has taken a significant step in transitioning from regular testing to Ultra tests across the entire country.

Question: Belarus annually purchases tests Xpert® MTB/RIF, Xpert® HIV-1 Qual, Xpert® HIV-1 Viral Load using funds from the Global Fund. PCR testing with the automated Xpert® system is conducted in clinics in almost all regions of the country, and doctors have a need to

expand the range of tests. Question: What is the approximate cost for Belarus of tests Carba-R, MRSA/SA Blood Culture, MRSA/SA SSTI, C. difficile, GBS?

Answer: As far as we know, these tests are currently not offered for sale in the ECA region. As of today, we cannot provide you with additional information. When something is known, we will inform you immediately.

Question: In Tajikistan, all regions and districts are equipped with GeneXpert devices, and local specialists have experience calibrating drugs. Unfortunately, there are problems with replacing parts that are supplied only by your company. For Tajikistan, sending and receiving parts by mail is very problematic, and it costs a lot of additional money. What can Cepheid offer for Tajikistan so that the devices do not stand idle waiting for repairs and we can address these issues ourselves?

Answer: We understand the difficulties faced by our customers in Tajikistan and recognize the importance of ensuring the uninterrupted operation of GeneXpert equipment. To improve the situation, we are willing to consider various forms of collaboration. One possible step could be discussing the organization of training for local specialists in Tajikistan to perform simple types of technical maintenance and parts replacement. This may include training programs to enhance the qualifications of personnel in the maintenance of GeneXpert equipment. Additionally, we can explore the provision of additional training materials and remote support.

Our goal is to ensure the effective operation of the equipment and support our customers. To initiate this process, we can start discussions with your local team to better understand the context and identify the best ways to address this issue in Tajikistan. Please provide us with contact information so that we can reach out to you for further discussions.

Answer: Tajikistan has been on a full-service contract for a long time, and all necessary parts were supplied free of charge according to the replacement plan. At some point, the warranty period of some systems expired, partly due to budget constraints. A decision was made at the country level that each case would be considered individually, as mentioned earlier. Delays were caused by the service not being included in the budget and unforeseen expenses. As far as we know, all cases of malfunctions have been addressed to date. At some point, we made concessions and provided parts for the equipment requiring service in advance for free.

We evaluate each request, considering its urgency, the need to restore the functionality of the equipment, and take various measures depending on the specific case. In the case of Tajikistan, we were able to be flexible, allowing for the simultaneous restoration of all equipment. As far as we know, a service budget is planned for the next year, and the systems will be transferred to full-service maintenance. The training that took place in July helped increase the number of specialists capable of performing module replacement actions in the country. Among other things, we trained two specialists from Tajikistan. In the future, we will discuss and decide on the service presence directly in the country. This depends on how ready the program is for the presence of a service partner in the country.

Question: We know that devices are idle for various reasons. The lack of repairs is the most frustrating reason. Have you talked to the Global Fund about including service maintenance in contracts when purchasing a device? It's very frustrating when large amounts of money are spent, and the device then collects dust. Instead of molecular diagnostics, people resort to the good old microscopy. This problem needs to be eliminated.

Answer: You have noted correctly. This work is carried out not with the Global Fund but with the Ministry of Health or non-profit organizations that procure equipment. We demonstrate the

benefits of purchasing equipment with service contracts. When Xpert Check kits are included in the service program right away, everything comes automatically. If you buy systems with reagents as part of special offers, it is cheaper than buying systems separately. With the money saved, you can purchase one or another service contract, and you will get a machine not with a two-year warranty but right away with five. In this case, the service is handled by Cepheid or a service partner. This issue is raised at every visit, but each country independently decides what is more important to them in a given year and what they are willing to spend the planned budget on.

Patient Community Representative's Comment: I am a member of the Global Fund's TRP (Technical Review Panel), and I see how many GeneXpert tests are procured under the Global Fund. I do not know how many are procured under GDF, PEPFAR, UNITAID, and other structures. Understanding the regional specifics, I can say that sometimes countries do not care whether the device will work. They are more concerned about the budget allocated. In Global Fund grants, there are many competing interests, and there are cases where something else is included instead of service. If this is left to the discretion of the country, decisions are not always made in favor of people and anti-tuberculosis programs because even the anti-tuberculosis program does not always have the final say.

Response: We hope that all present colleagues will note this point. Service is usually the area where cost-cutting occurs. Unfortunately, over time, this has a reverse effect. We will continue to HBDC
work proactively with Global funders to ensure the highlight the importance of service. We are constantly innovating and will communicate any additional service offerings that the company may offer.

Question: Most of the equipment is idle, not working, etc. Is work being done with the Federal Penitentiary Service (FSIN), as they are separate from the Ministry of Health? FSIN does not allocate funds for service at all. This is happening everywhere. From our side, it is important to monitor in which countries how many machines are not working and for what reasons. If the Global Fund understands that service needs to be included in the contract, then states do not understand this. The question of price is also important because the state budget often cannot cover the expenses covered by PEPFAR or Global Fund projects, especially in Kyrgyzstan. This becomes a problem when transitioning to state financing.

Answer: If we look at service statistics from country to country, service is more frequent in FSIN institutions than in other government organizations because the system is organized a bit differently there. We are surprised that the equipment is idle there. If you have such data, please share it. During the training we conducted this spring in Azerbaijan, representatives from FSIN were present, and we monitored the situation there. All superuser training sessions are provided free of charge. Representatives of end-users, including national programs interested in equipment servicing, can participate. We accept applications for participation in training sessions.

Patient Community Representative's Comment: There can be various reasons for equipment downtime. For example, the departure of specialists who know how to operate the equipment. Monitoring is needed for the reasons why this happens.

Question: I participated in organizing Cepheid's GeneXpert training in Uzbekistan and attended the training myself. Does the company conduct knowledge exchange events with laboratory specialists from Uzbekistan?

Answer: Such training sessions were held in the country from 2010 to 2020. Today, this practice continues. The last presence in the region was training in Azerbaijan, before that in Kyrgyzstan, before that in Tajikistan last year. Every time we talk to the national program or the Ministry of Health, we ask about the need for training and offer various options. We either train laboratory specialists on-site in the region or offer training at our training centers, depending on what is more convenient in terms of the country's budget. We are moving away from the practice of online training, which was the only option during the Covid-19 epidemic. Now we offer in-person training. The best option is when there is an opportunity to visit a training center where you can see all our equipment, work with all the kits, ask all possible questions, and get all the support on-site. If it is expensive for the country, we can bring a trainer to the country. But then the program takes care of the necessary organization and delivery of the test machine to the training venue.

Comment: Often, people who later leave their jobs participate in such training. In Tajikistan, there is a significant brain drain. I was a member of the TRG, and I had a question: where are the specialists they trained? Machines stood idle because there was no opportunity to purchase equipment. In Tajikistan, there is no DHL, and there is one postal service for the whole country, which creates certain barriers.

You say that you discuss these issues with the Ministry of Health. Why are there no alternative options? You can create competition by involving international organizations and civil society. When developing a new budget, we argued with the Ministry for a long time that we also need a service contract.

When we implemented the Global Fund project, we asked many questions about equipment purchase and maintenance. We understand that when buying equipment, we should know about copyrights, how to service this equipment on-site. You have seen big cities; the situation is different in regions. There are cases, and the biggest problem is in GBAO (Gorno-Badakhshan Autonomous Region) and the Khatlon region, when a lot of equipment is idle, and representatives of the regions state that they have no tuberculosis patients, drug users, and MSM. There are regions where your company needs to involve civil society activists and international organizations. We are now monitoring project implementation and understand that large funds are coming into the country, but a lot is going by. We ask you to take this into account next year. Demand, like us, from the Global Fund and those implementing the project that they include service contracts in the agreements. Perhaps the Ministry of Health will tell you that everything is fine, and we trained two employees, but we ask you to actively monitor specifically in Tajikistan.

Answer: From our side, we do everything possible to maximize service coverage in this region and work on prevention. This applies to Tajikistan, Kyrgyzstan, and Uzbekistan. We talk more often with ministries because they are the ones who allocate the budget and know where to direct it. We try to convey requests "from the field" to them. From year to year, we make special offers. Our job is to show their economic efficiency. If you already have planned expenses for equipment, and you managed to get it with a discount, then this discount can be directed to the same service. Tuberculosis tests are now 20% cheaper, so next year these 20% will be directed somewhere. Now is the time to plan part of these funds. In Uzbekistan, we also see the need for service presence. Currently, we are considering several service companies that we plan to involve to ensure maximum fast service coverage. We saw this need a year and a half ago, but then representatives of the national program told us that they were coping on their own.

Question: In Ukraine, there is only one service engineer. This information comes from doctors who work "in the field" directly with this equipment. They say that equipment often stands idle just because there is only one engineer. Ukraine is a huge country, timely diagnostics are very

important. We know that when the equipment arrives, it cannot be unpacked and installed without an engineer. Equipment also needs maintenance. If there is only one engineer, he needs to constantly travel from one point of Ukraine to another. How will you comment on this? You mentioned that in Ukraine, there is an individual entrepreneur with employees. At the same time, you also said that you license engineers and the organization. However, an individual entrepreneur largely does not represent an organization.

Answer: We have been working with individual entrepreneur Skripov for over 10 years. He is the best in the region in terms of providing service to end-users. His service company is compared with others based on certain metrics on a monthly basis. To date, he is the leader among service companies. Now, our partner from Kazakhstan is very close to him; they compete for the title of the best. To ensure that Mr. Skripov can timely perform equipment maintenance and repair, a spare parts reserve has been formed for him, which is located in the country. Despite restrictions on importing goods into the country due to the current situation, he has a sufficient stock of spare parts so that the equipment does not stand idle in principle. We make sure that his knowledge is constantly updated, and this applies to his employees as well. At least every two years, we renew certificates through testing and recording the results. Our service contracts cannot last more than three years, so every three years, service partners undergo certification and assessment of how well the partner can provide service support at the current level. If something is idle, and you see that the service partner is not coping, ask Cepheid directly, and we will take immediate action.

Question: What challenges exist in translating instructions and other materials into national languages in the EECA countries?

Answer: The basic language for translating instructions is Russian, and all instructions are translated into Russian. If there is a need according to national standards, we translate into the national language, as we do in Ukraine. We handle translations within the company, and if we cannot manage, we involve authorized translators. We do not do this in advance and focus on countries where it is genuinely required by legislation. All instructions are available and open. If a new test is released, translating the instructions is a matter of time. We also translate into all European languages.

Comment from a patient community representative: We urge you to prepare translations into national languages in advance because the use of the Russian language is decreasing in the region, particularly in Central Asia, Moldova, etc. Even if there is no legislative requirement for translation into the national language, de facto, the absence of instructions in the national language can be a significant barrier at the level of people working with the device.

Answer: Thank you very much for the comment. We will definitely bring this up for discussion in the committee regarding our presence in the region because it is indeed important.

Question: The first two times, the validation of the cartridge system's operation can be performed by an engineer on-site, while subsequent system checks should take place at the manufacturer's plant. Does Cepheid have plans to develop initiatives for localizing the cartridge validation process within a country to reduce financial and time costs for the country?

Answer: Perhaps you are referring to the validation of modules, as we cannot perform cartridge validation outside the manufacturer's plant. The Xpert Check kit allows assessing the condition of each specific module based on various parameters, including temperature, mechanical factors, and others, determining the module's functionality today. As a result, it can be understood whether the module needs replacement now or in the near future. The option of module restoration in the country is currently unavailable because specific calibration actions

must be carried out at the module restoration center. We had plans to transfer cartridge restoration centers to some countries. This is quite a complex technological process. Currently, we do not see the need for it. We monitor the number of modules in the region and focus on logistics to ensure that spare parts are delivered on time or maintain buffer stocks, which is much better for the economy. In this case, you can come to the warehouse, return your module, and receive a new one.

Question: How does insufficient use of the GeneXpert system affect its service maintenance, especially in cases where the system has not reached its potential? Should a system that, with a potential for more than 3000 sample tests for 4-module systems, has only performed 100 sample tests undergo the same service maintenance as a system that has reached its maximum potential?

Answer: For each device, there is a specific maintenance algorithm that includes procedures described in the user manual. These procedures involve daily, weekly, monthly, quarterly, and yearly tasks, as well as maintenance as needed. There are two criteria we apply to assess module performance and quality. Annual maintenance and Xpert Check should be done either once a year or every 2000 tests, depending on which occurs earlier.

Question: So, even if the system has been idle for a year and only three tests have been conducted on it, after a year, it still needs to be checked as if it had performed 2000 tests? Or does the resource usage take precedence over the standing time?

Answer: No. This can be compared to car maintenance: either mileage or time. There are specific things that need to be checked – resource, optics, the tendency to fade, plastic's tendency to crumble, etc. The time factor plays a role, and we cannot influence it.

Question: Is it possible to use GeneXpert systems in mobile clinics, and how do factors such as constant movement in a vehicle and changes in operating conditions affect the systems' performance?

Answer: Using it in mobile laboratories is not prohibited by the user manual or equipment requirements. When conducting tests, all requirements specified in the user manual must be followed. The equipment should be on a stable surface to avoid shaking. Shaking itself should not damage the equipment, but for transportation, we recommend using special transport cases that we also supply. These are large boxes made of reinforced plastic containing foam inserts to ensure maximum equipment safety. When transporting equipment from place to place, environmental requirements need to be considered: dust, humidity, etc. Laboratories typically control this with air purification, air conditioning, and protective covers. Mobile laboratories have specific requirements.

Question: Are there temperature requirements?

Answer: This is written in the operator's manual. For the equipment to function correctly, the temperature should be between 15 and 30 degrees Celsius. For storage, the temperature range is slightly wider.

Question: So, if the device is transported in the cold and then used in cold temperatures, will the device withstand it?

Answer: We cannot answer this question right now and will get back to it later.

Question: Is there a plan to launch the production of GeneXpert Omni for small regions with a low number of tests per year? What measures are taken to reduce the cost of the GeneXpert

Omni device? Is it possible to reduce the cost of reagents? If yes, by how much, and what factors does it depend on?

Answer: The Omni project was officially discontinued in 2022. The reason for discontinuation was that the Omni cartridge was different from GeneXpert. Therefore, implementation and registration would have taken too much time. We currently have the GX II platform available.

Question: Do you have plans to transfer patents and technologies to other companies? Do you intend to abandon patents?

Answer: The current strategy of Danaher and Cepheid is to continue the development of GeneXpert under the protection of our patents. We have spent over 12 years developing the service ecosystem, and we are not ready to give it up. Accordingly, we do not plan to transfer technologies to other manufacturers. We welcome competition, but we believe in the GeneXpert platform and that our strategy will prove itself.

Question: Are you considering the possibility of a Nespresso-like model, where the machine is original, and capsules can be supplied by other manufacturers? This could be a good step to increase accessibility.

Answer: We have received comments regarding Nespresso before. Currently, the strategy is that we produce all components, including cartridges, directly by the efforts of Cepheid and Danaher. We had the experience of producing the Resistance Plus® MG FleXible cartridge for the detection of *M. genitalium*+ macrolide resistance. However, it is important to note that unlike Nespresso, medical devices are highly regulated and importing medical equipment into the country requires significant investment and overcoming substantial regulatory barriers.

Question: Your access program is designed for Africa and Pakistan. Do you have plans to expand to our region?

Answer: Such plans existed and still do. We presented the AccessCare proposal in Ukraine a year ago. There are plans for other countries as well; the program is open and available. We made specific calculations and presented them to the country. Currently, the budget for transitioning to such a program is not planned in Ukraine. Kazakhstan has decided to limit itself to a service contract. If someone wishes to adopt this program, we will be happy to present it and find ways to implement it. In countries where it has been implemented, the results are very good.

Question: Do you have any charitable programs, including for Ukraine? This concerns both service maintenance and the supply of cartridges.

Answer: Cepheid supplied cartridges to Ukraine for tuberculosis, HIV, and Covid-19 as soon as the war began. The delivery was carried out through UNDP. Machines and cartridges were supplied and installed for free. The already installed machines were serviced under the contract.

Question: Many organizations in the ECA region supported the Time for $5 campaign. In this regard, please tell us about the prices and plans for expanding access in the ECA countries. Does Cepheid take into account that many countries in the region are transitioning from donor financing to state financing when forming pricing policies for the GeneXpert system and service?

Answer: On September 20, 2023, we announced a price reduction to $7.97. This is the cost price. Every year, we will undergo a third-party audit by the Global Fund. The Global Fund will verify whether this price indeed corresponds to the cost price.

Question: Will countries in our region be included in the list of 144 countries, and if yes, when?

Answer: The price is valid from September 20. It may be challenging to make changes to some existing contracts due to their conditions, so we will adjust them at the old prices, and new contracts will be concluded at the new prices.

Question: Do you have a methodology for determining the price? Will it be public? Will the price be reviewed annually since some cost components may change?

Answer: The price can change depending on many factors and variables. Our company provides all the information to the Global Fund. The Global Fund will be responsible for its distribution and publication. As far as we know, the methodology will not be public, but we will clarify with management.

Patient community representative's comment: Perhaps the introduction of a new plant in India will affect the price.

Answer: It's important to note that the launch of new production in India surprisingly contributed to a slight increase in the price. Until certain processes are established, the price will remain slightly higher.

Question: Are there discount or preferential programs for specific patient groups in commercial institutions?

Answer: As we mentioned, we provide some special conditions for the commercial sector, but this is always coordinated with the national tuberculosis program within the public-private partnership framework.

Question: What registration challenges do you observe in the ECA region, including in the EAEU countries?

Answer: The registration process under the EAEU rules keeps us on our toes all the time because no one understands when these rules will finally come into force. Therefore, in each country, we follow the rules that are currently in place and try to respond promptly to changes to ensure uninterrupted product supplies. Registration is not required in all cases. In particular, it is not mandatory for the HBDC program. Therefore, countries where national programs or non-profit organizations receive our products as part of humanitarian projects without registration are not represented in the so-called "registration presence list." In several countries, such as Belarus, Ukraine, Moldova, Georgia, and Kazakhstan, registration is required, and we update registration certificates to avoid supply disruptions. We take proactive steps to obtain registration certificates in advance so that products can be supplied as humanitarian aid when appropriate humanitarian channels become available. Currently, we have started working in Uzbekistan and Kyrgyzstan. This work is carried out by Cepheid. If necessary, we involve relevant authorized companies and investigate local processes.

Question: About two years ago, we started a discussion with Cepheid regarding service centers in Kyrgyzstan and Tajikistan. How has this process progressed? The equipment imported as humanitarian aid is in place, and modules enter the country under temporary importation. The code on the modules indicates that they entered the country as humanitarian aid and should stay in the country, and formally, we return the modules. How is this issue resolved?

Answer: There are different solutions to organize the recovery of modules and supply of functional modules. For example, in Uzbekistan, products were imported as humanitarian aid, and accordingly, they became the property of the state. It is impossible to change this status. For such purposes, there are temporary export and import regimes, where we take defective modules to the factory and restore them to fully operational condition. Then, having received the calibration certificate, we return the same modules to avoid violating the country's legislation. Recovering the module transferred to us takes literally two days longer than if we received a faulty module from you and sent a working one in return.

Question: What product are you registering in Kyrgyzstan? Have you managed to submit a registration dossier? You probably know that the national registration procedure under a special decree in Kyrgyzstan is valid only until the end of the year, and then we must return to the EAEU rules.

Answer: We have not submitted it yet. Consultations are currently underway.

Question: Will you be able to submit it by the end of the year?

Answer: We cannot say at the moment.

Question: Do we understand correctly that you do not like the EAEU procedure for several reasons, and you choose national procedures?

Answer: It's not about loyalty to a particular procedure but about following the letter of the law.

Question: Is the development of new cartridges to detect resistance to bedaquiline and pretomanid on the GeneXpert diagnostic system underway? If yes, when can they be expected on the market?

Answer: Cepheid continuous to innovate and create new tools to address resistance in TB. At present we do not have Bedaquiline or pretomanid cartridges in the pipeline.

Question: Please tell us about IVDR.

Answer: Below is the IVDR roadmap for Xpert tests, which includes more than 30 tests. It provides information on which tests we have applied for registration. We expect the registration of the portfolio for HIV and hepatitis first, tentatively in May 2025. The respiratory diseases portfolio is expected to be registered around the same time. Portfolios for oncology, genetics, women's health, sexual health – May 2026. Hospital-acquired infections – May 2026. Tuberculosis – 2026, another respiratory disease portfolio – May 2027. This slide demonstrates that the registration process in countries is becoming more complex. We will keep you updated as the process progresses.

Patient Community Representative's Comment: We asked you to send a table with the registration status of products in countries. We ask you again to provide this information. We urge you to come in person next time. We invite you to meet with our representatives at the World Conference on Tuberculosis to discuss various issues, including the press release.

Answer: We couldn't attend in person due to the decision of the legal department, but in the future, we hope to meet with you in person. We will consider your suggestion to meet at the conference; it's a good opportunity to address activists' questions about the press release.

End of the meeting.