Annual Report 2024

Q-LINEA

Contents

The English version of the Board of Directors' Report and Financial Statements will be published on May 22, 2025 at www.qlinea.com Until then, we refer to the Swedish annual report.

2024 in brief

Q-linea develops groundbreaking infection diagnostics that benefit patients, the healthcare sector and society

Q1

- The Company was awarded a public tender for rapid AST instruments and consumables issued by Fondazione PTV in Italy.
- Q-linea successfully finished the clinical trials required to add the drug Meropenem-Vaborbactam to its existing ASTar panel.
- The Company announced that Stuart Gander would take over as CEO of Q-linea and that Anders Ljunggren would take office as Managing Director of Q-linea AB in Sweden on 1 March 2024.
- Q-linea initiated a cost-saving programme with anticipated savings of SEK 50 million annually.
- Q-linea created a separate subsidiary for Podler.

Q2

- Q-linea received US FDA 510(k) clearance for the ASTar® System on 26 April.
- Q-linea applied for a NTAP code for the US market.
- Q-linea announced that the technology behind Podler has been valued at SEK 70 million. The valuation is based on a report carried out by an external analysis company.
- The company was offered an increased and extended loan facility by its main owner Nexttobe. Total facility, when utilized, amounts to SEK 101,500,000. The loan facility runs up until 30 June 2026.

Q3

- The Company participated in its first public tender in Belgium.
- Two American hospitals presented ASTar data in line with good results shown in several European studies.
- CMS granted New Technology Add-on Payment (NTAP) for ASTar with a reimbursement of USD 97.50 per eligible patient.
- Q-linea expanded its operation to Romania and the Middle East through two new distribution agreements.

Q4

- Q-linea announces changes in the management team and further expands the commercial team in the US.
- Large U.S. reference laboratory completes evaluation of the ASTar system and the first clinical evaluation of ASTar begins at a cancer center in the United States supported by National Cancer Institute (NCI).
- Two commercial evaluations in the UK are completed.
- The Company receives a request for a contract from a prominent hospital in Milan and participates in a multi-center procurement in Italy.
- Q-linea resolves to carry out a rights issue of approximately SEK 225 million in Januart and enters into an agreement for a bridge loan facility of approximately SEK 40 million.

After the end of the period

- The company publishes a company and market update with the main message that 30 – 40 instruments are expected to be contracted by the end of 2025 and that another 60 – 90 instruments are placed in 2026.
- The company signs its first two agreements with customers in the United States.
- Q-linea signs a framework agreement with a large national American reference laboratory.
- The company wins the first tender in Belgium and wins another tender in Italy.
- Q-linea announces the outcome of the rights issue, subscribed to 90.5 percent, corresponding to approximately SEK 204 million before transaction costs. In total, the Group received cash of approximately SEK 93 million after transaction costs, set-off of loans and repayment of bridge loans.
- The company announces that the first clinical evaluation in the Gulf Cooperation Council region of ASTar has been initiated at Sheikh Khalifa Medical City, Abu Dhabi (UAE).
- Q-linea publishes a communiqué from the Extraordinary General Meeting on April 3 where a decision was made to reduce the Company's share capital with the primary purpose of enabling a discount in the future exercise of warrants of series TO1.

Q-linea, sepsis and ASTar in brief

Q-linea in brief

Q-linea is a world-class leader in developing rapid Antimicrobial Susceptibility Testing (AST) technologies used in the treatment of bloodstream infections and sepsis. Hospitals use ASTar® to significantly reduce the time to optimal antimicrobial therapy and ensure that patients receive the correct treatment sooner. We help create sustainable healthcare, now and in the future, and safeguard the effectiveness of antibiotics for generations to come. Q-linea is headquartered in Uppsala, Sweden and has regional offices in Italy and the US, as well as a network of partners in Europe and the Middle East.

Sepsis in brief

Sepsis is a life-threatening condition where the host's immune system overreacts to an infection, causing damage to the body's tissues and organs[1]. Bacterial Bloodstream Infections (BSIs) are a common cause of sepsis. The underlying infection must be treated as soon as possible to minimise harm. Research has shown that each hour of delayed appropriate antimicrobial therapy reduces a patient's chances of survival and increases the risk of long-term complications[2]. Treatment success depends on optimising antimicrobial therapies with guidance from AST.

About ASTar – ASTar enables a sought-after paradigm shift

ASTar is a fully automated, phenotypic rapid AST system that delivers actionable results faster than traditional AST methods. The ASTar Instrument and ASTar BC G- Kit test the susceptibility of Gram-negative bacteria, including fastidious species[3], against a broad spectrum of antibiotics, and deliver a comprehensive report of detailed treatment recommendations clinicians use to optimise patient treatments.

Our history and future

Q-linea was founded in **2008** by scientists from the Rudbeck Laboratory at Uppsala University, together with Olink AB and Uppsala University's holding company, UUAB. The Company initially focused on biosecurity applications using proprietary technology for molecular identification of bacteria and viruses.

In **2012**, Q-linea entered the in vitro infection diagnostics business with innovative technologies for rapid and sensitive analyses of nucleic acids and proteins. A partnership with risk capital firm Nexttobe ensured long-term financing and technological progress.

In the following years, bacterial identification from positive blood cultures using technologies like mass spectrometry revolutionised the field of infection diagnostics. This led to the development of ASTar, a fully automated rapid AST system that tests directly from positive blood cultures, complementing rapid ID systems.

Q-linea was listed on the stock exchange in **2018**, and ASTar was launched in Europe in **2021**. In **2024**, ASTar received FDA approval and was launched in the US. During this time, multiple clinical and sales partnerships were established worldwide.

The ease of use and power offered by ASTar remains unmatched in the field. Future developments of the system will include the analysis of isolates and expansion of the antimicrobial panel.

We continue to support healthcare professionals and their patients, and strive to redefine the gold standard for rapid susceptibility testing to improve the care of patients with serious infections.

Footnotes—see References on page 84.

Employees

Q-linea has a dedicated team with extensive knowledge and experience from various disciplines. At year-end, the Company had 94 (127) employees, of whom 41 (53) were women and 53 (74) were men, as well as 4 (3) consultants. Seven employees are based in the US and three employees are based in Italy for commercial activities. Two consultants are based in the US. Q-linea focuses on strategic partnerships for technical evaluation and providing additional expertise, as well as market expansion. The Company has state-of-the-art facilities at two locations in Uppsala.

Vision

Q-linea helps to save lives by ensuring antibiotics continue to be an effective treatment for future generations.

Mission

Q-linea develops and delivers innovative solutions for healthcare providers, enabling them to diagnose and treat infectious diseases in the shortest possible time. The Company's solutions help healthcare providers worldwide to reduce the use of antibiotics by providing optimal treatment information for each patient.

Business concept

Q-linea develops and delivers solutions for healthcare providers, enabling them to accurately diagnose and treat infectious diseases in the shortest possible time.

Strategy

Q-linea has built up robust competence and infrastructure in order to develop and supply integrated diagnostics systems. Sales are made directly and via partners, with the majority of income expected to come from sales of consumables.

Commercialisation strategy

During 2024, Q-linea has broadened and deepened its commercial engagement with the market. FDA clearance in April was pivotal to enabling the full marketing of the ASTar platform in the US, and the company continues to build its commercial team for direct sales and marketing in the largest global market. Q-linea has segmented the thousands of US labs to focus initially on the most promising candidates for ASTar early adoption which skew towards larger, academic hospitals, integrated delivery networks and regional and national reference laboratories. Collectively this first wave of target customers comprises 25% of all US blood stream infection patient testing. Once traction is gained in the US market, the company will continue to expand the commercial team and broaden its market outreach to target the 'next 1,000 labs' that comprise 60% of US volumes and have the patient volumes to support ASTar testing.

In parallel, the company has been active in strengthening its presence in the EMEA region. Earlier investments in direct sales in Italy have begun to bear fruit with the first three commercial placements of ASTar in Europe being in Italy. Q-linea continues to work with existing partners across the Nordics and Western Europe to build and convert a pipeline of interested users. Additionally, we are executing on our strategy to 'follow the patient' into the markets with highest AMR need with distribution partnerships in Eastern Europe and the Gulf states that are expected to generate sales during 2025.

A platform for growth

2024 was a significant year for Q-linea following a general theme of transition from a development-oriented company to one focused on commercialising our flagship ASTar® platform

Opening the key US market

Our most important development during the year was the commercial launch in the US market which represents over 50% of the global opportunity by value. Following FDA clearance in April we rapidly engaged with the top 300 hospitals and labs in the country to introduce ASTar. This targeted approach has yielded a sizeable pipeline of interested customers with a calendar of planned evaluations through early 2025. Confirmation of NTAP funding (USD 97.50 per patient, available for Medicare patients in US hospitals) from the federal agency CMS, which is unique to ASTar, bolsters the economic proposition for ASTar which is already the leading technical solution for rapid antibiotic susceptibility test (AST) on the market. Early demand has been strong and Q-linea has steadily built up our commercial team in the US to meet the market. Contracting timelines can be unpredictable, but we welcomed our first US commercial sale in early January, just nine months after FDA clearance.

Supporting evidence of clinical benefits

In our field, clinical impact is the ultimate determinant of value, and we were pleased to see a steady cadence of clinical evidence emerging from our co-sponsored trials in Italy, Belgium and the US which all mutually reinforced the core insight that ASTar can reduce time-to-result by 30 hours or more. In particular, our investment in the four-site LIFETIMES health economics and outcomes research (HEOR) study is a pioneer in our field. We look forward to complementing the initial findings presented at AMCLI and ESCMID in 2024 with further insights on the economic benefits of ASTar emerging from the second phase in 2025. Q-linea has been an active thought leader in the rapid AST space with poster and podium presentations across the major global and regional conferences.

First clinical patients treated in Europe

The first commercial installation of ASTar was completed in Q1 2024 and has been generating clinical results for patients in Rome ever since. Two additional sites have since been added in Italy with more anticipated soon. Italy is the fastest-moving country in Europe owing to the high clinical burden of AMR and we anticipate other major European markets to follow as rapid AST demonstrates its clinical and economic impact.

Establishing the next avenues for growth

Our new agreements with partners in the Middle East and Eastern Europe have moved quickly and are already building up customer interest with expected results in 2025. We also streamlined our development pipeline, concentrating resources into several high-impact projects for delivery in 2024 and early 2025. Q-linea will continue to be at the forefront of innovation in AST with new drugs and sample types under development and are informing our priorities based on the surge of customer input received on the back of our in-market engagements. The field remains highly dynamic, and we are pleased to see the positive response from customers to our current platform and planned innovation funnel.

Strengthening the organisation

Following the theme of transition, we conducted a successful cost-cutting program during the first part of the year which reduced development and overhead costs. A portion of the savings were reinvested into commercial capacity for a net cost reduction of approx. 40 MSEK annually. Our leadership team has evolved considerably during the year.

Financing

We concluded the year with a well-subscribed rights issue which in combination with a directed issue raised approximately 216 MSEK in new equity before transaction costs. This provides us with resources needed to continue pressing our commercial advantage in the market. I would like to especially thank all the employees who left during 2024 who have made major contributions to Q-linea over the years. We have likewise welcomed new members of the team who join with fresh ideas and a shared yearning to bring ASTar to patients during 2025.

Uppsala, 27 February 2025

Stuart Gander, CEO

The field remains highly dynamic, and we are pleased to see the positive response from customers to our current platform and planned innovation funnel.

Stuart Gander, CEO

Sepsis is an overreaction by the immune system

Sepsis is a complex life-threatening condition where the body's immune system overreacts to an infection. Without prompt treatment, this progressively toxic inflammation can cause severe organ damage and death.

Any infection can cause sepsis, but bacterial Bloodstream Infections (BSIs or bacteraemia) are a common cause, as bacteria spreading through the body can affect multiple organs quickly and simultaneously.

Every year, sepsis affects around 50 million people worldwide and causes 11 million sepsis-related deaths. This makes sepsis responsible for 1 in 5 of all global deaths, more than breast, lung, and prostate cancer combined. Nearly half of all sepsis cases are in children under the age of five[1].

Rapid and accurate diagnosis and treatment are crucial for patient outcomes as every hour of delay in appropriate therapy greatly increases the risk of complications and death. Septic shock is a severe complication marked by dangerously low blood pressure and metabolic abnormalities – 40 % of patients with septic shock die[2]. Many sepsis survivors are left with physical and psychological complications that severely impact their quality of life.

Antimicrobial Susceptibility Testing (AST) results help refine therapy through tailored adjustments. E.g., antibiotic escalation, de-escalation, and dosage adjustment. Unfortunately, conventional AST methods can take upwards of 48 hours during a time when every hour is crucial. Sepsis is the most expensive disease to treat in the United States, averaging $32,000 per patient and exceeding $60 billion annually[3-4].

ASTar – our futureproof AST system

ASTar is our rapid AST solution. A fully automated system for rapid AST based on broth microdilution (BMD) that requires only two minutes of hands-on time.

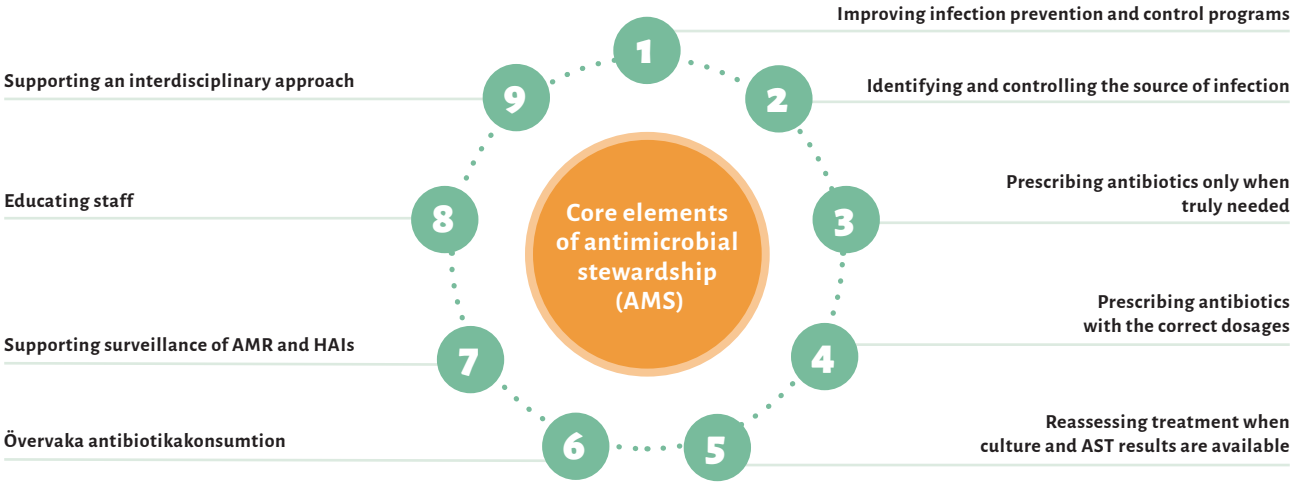
The initial application of ASTar is the analysis of Gram-negative bacteria from positive blood cultures from patients suspected of having a BSI or sepsis. ASTar can be used alongside rapid bacterial ID systems, together to meet the need for early therapy optimisation. Actionable AST reports are delivered in approximately six hours, enabling antibiotic adjustments up to 48 hours earlier than traditional technologies, so patients can receive tailored, optimal therapies sooner[5].

The instrument software is kept up to date with the latest clinical breakpoints, and the AST testing disc is designed to allow for future expansion with new antibiotics. This ensures that ASTar is ready to meet future needs in infectious disease diagnostics and remains an invaluable tool for AST and antimicrobial stewardship programs.

Antimicrobial resistance – a global health crisis

Antimicrobial resistance (AMR) is the process by which pathogens stop responding to antimicrobial treatments that previously worked. A common infection could escalate into something much more serious – posing not only concerns for the individual but also societal risks. AMR is a global health crisis affecting millions.

Examples of strategies used to reduce the spread of antimicrobial resistance



Footnotes – see References on page 84..

There are an estimated 5 million global deaths associated with bacterial AMR every year and AMR is predicted to become the leading cause of global death by the year 2050. 1 in 5 deaths from AMR are in children under the age of five1,2.

Many species of bacteria are intrinsically resistant to certain types of antibiotics, and most can develop resistance to antibiotic treatments when under selective pressure. These bacteria are much more challenging to treat, lengthening hospital stays, raising medical costs, and increasing patient mortality.

Treating resistant infections requires the use of more potent antimicrobials with no guarantee further resistance will not emerge. With every new development of resistance, the tug-of-war between effective and ineffective treatments is reset.

Combating AMR with AST

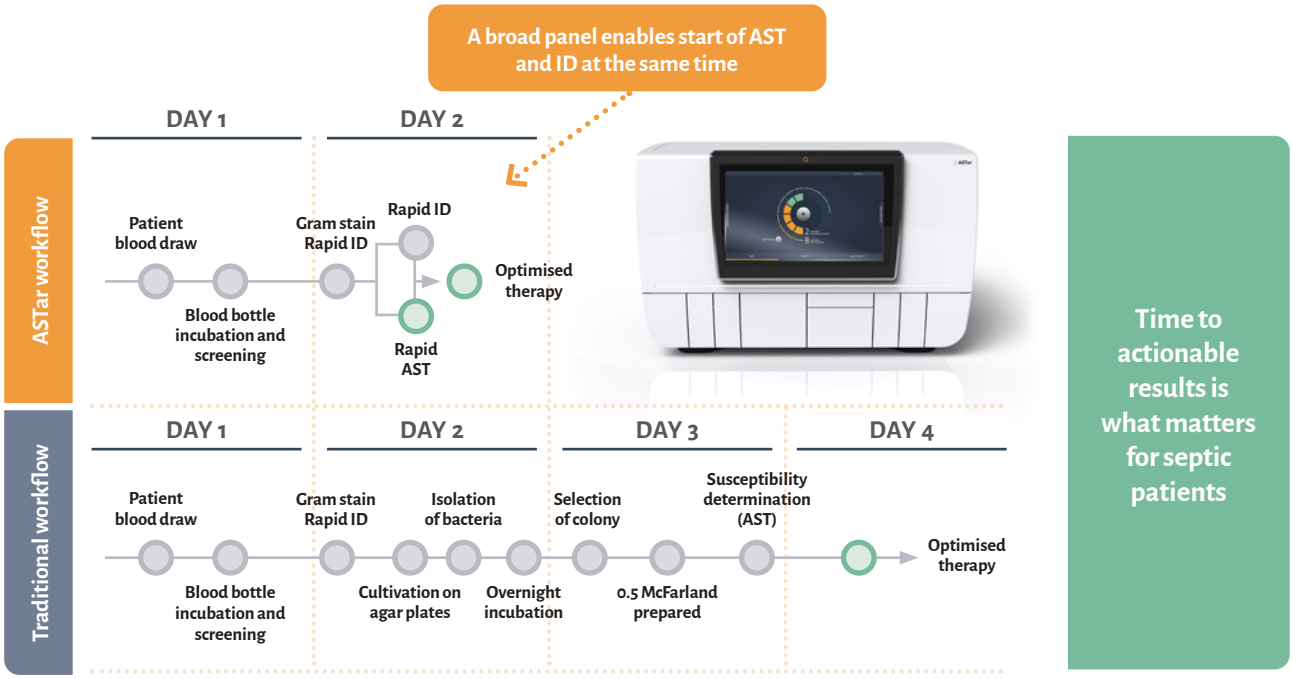
Addressing AMR requires a coordinated stewardship effort to promote responsible antimicrobial use and investment in rapid diagnostics. Faster AST technologies can shorten the time to optimal patient treatment and help prevent the emergence of individual and societal AMR by minimising the use of broad-spectrum antibiotics. This improves patient outcomes and helps preserve the effectiveness of existing antibiotics.

AST technologies must be easy to update and expand based on the ever-evolving requirements set by AMR and clinical demand. Drug panels and pathogen coverage should be readily adaptable, a feature ASTar provides.

Large laboratories have unmet needs

There is a vast need for rapid treatment recommendations in cases of infectious diseases, a need that is not being met in the market today.

Results up to 48 hours faster



To meet the daily sample throughput at a large laboratory, a system should handle 10–30 positive blood cultures per day. In addition, blood cultures may signal positive during the night, which means that a system needs high peak capacity. 24/7 laboratories have a need for random access to be able to quickly start and run a sample any time it signals positive.

ASTar is easy to use and fully automated, with an intuitive and user-friendly interface, so that it is quick and easy to start and to obtain results. ASTar can analyse up to 12 samples simultaneously and offers continuous random access. ASTar can be run in parallel with any rapid pathogen ID-solution. Input of pathogen ID is needed to create the final results report.

“ASTar has proven to be a game-changer in our laboratory”

Prof. Cartesio D'Agostini, Policlinico Tor Vergata, Rome, Italy

What was your first encounter with Q-linea and ASTar?

My first encounter with Q-linea and ASTar was at ECCMID 2022 in Lisbon. I immediately recognized the potential of the instrument. In the following years, I stayed in touch with the sales network, and as soon as the opportunity arose, a tender was initiated to acquire an instrument for rapid antimicrobial susceptibility testing. It was crucial to choose a system with the ease of use that ASTar offers.

You've had some hands-on time evaluating ASTar: Can you tell us a bit about the study?

The ASTar system was quickly integrated into our routine workflow, and during the initial months of use, we conducted a comprehensive evaluation of its performance compared to our standard of care. The results have been incredibly promising, exceeding our expectations and demonstrating the system's reliability and efficiency in rapid antimicrobial susceptibility testing. We're thrilled to share that these findings will be presented at the national AMCLI congress in Rimini in March 2025. This represents an exciting milestone for us, as ASTar has proven to be a game-changer in our laboratory, enhancing both our diagnostic capabilities and overall efficiency.

Why was it important to implement rapid AST?

Implementing rapid AST was crucial due to its significant impact on patient management and antimicrobial stewardship. Rapid results mean we can provide targeted therapy much sooner, improving patient outcomes and reducing the risks associated with inappropriate or delayed treatment. From an antimicrobial stewardship perspective, it plays a pivotal role in combating resistance by minimizing the misuse of broad-spectrum antibiotics. This not only benefits individual patients but also contributes to public health by preserving the efficacy of existing antimicrobials. In today's healthcare landscape, having an instrument like ASTar is more than an advancement, it's a necessity.

Which features of ASTar are most appreciated by the lab and the clinical staff?

The ease of use is certainly one of the most appreciated features of ASTar, as it allowed us to quickly integrate the methodology into our routine workflow. This simplicity has been a game-changer for our team, ensuring smooth implementation and minimal training requirements. Additionally, the reliability and high concordance of the results with standard methods have been highly valued by both the laboratory staff and clinicians. These features provide confidence in the system's accuracy, ultimately supporting better clinical decision and enhancing overall patient care.

How has ASTar helped the hospital?

ASTar has significantly helped the hospital by reducing turnaround times for test results, which in turn has shortened patient hospital stays. This will bring tangible benefits both for patients, who receive faster and more targeted treatment, and for the hospital, by optimizing resource utilization and reducing overall costs.

Do you believe that ASTar can impact patient outcomes?

Absolutely, I believe ASTar has the potential to impact patient outcomes. By delivering rapid and reliable results, it enables earlier and more precise adjustments to antimicrobial therapies. This can lead to faster recovery times, reduced complications, and overall improved patient care. Furthermore, the contribution to antimicrobial stewardship helps combat resistance, ensuring that patients receive the most effective treatment while preserving the efficacy of antibiotics for future use. The combination of these factors underscores ASTar's ability to make a substantial difference in patient outcomes.

Thank you for sharing your insights about working with Q-linea and using the ASTar System, is there anything else you would like to add?

Thank you! I would just like to add that the implementation of the Gram-positive panel will be a key step in further expanding the use of ASTar. It will allow us to address a broader range of clinical needs, enhancing its value as a comprehensive tool for rapid antimicrobial susceptibility testing. We're excited about the potential this addition brings for improving diagnostics and patient care even further.

ASTar was developed for high sample throughput, and it offers the ability to handle peaks in the sample flow.

ASTar Instrument

ASTar is a fully automated instrument providing accurate and reproducible sample preparation followed by imaging of bacteria in the presence of select concentrations of antibiotics using a high-quality optical system. Input of Bacterial ID information is necessary to obtain results and access expert rules that help guide treatment decisions.

ASTar BC G- Consumable Kit

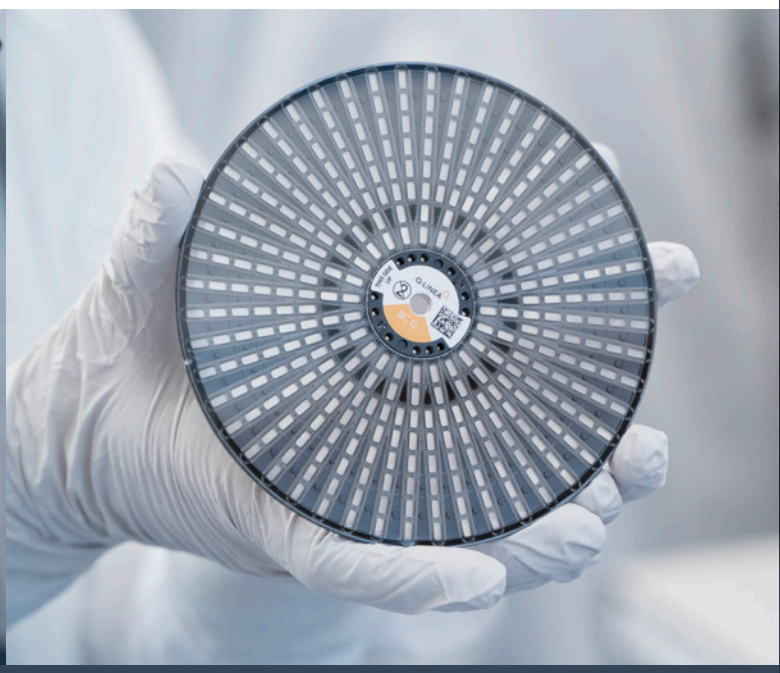
ASTar BC G- kit has two parts: a sample preparation cartridge and an AST disc. A frozen insert containing reagents is added to the cartridge before use.

The Cartridge

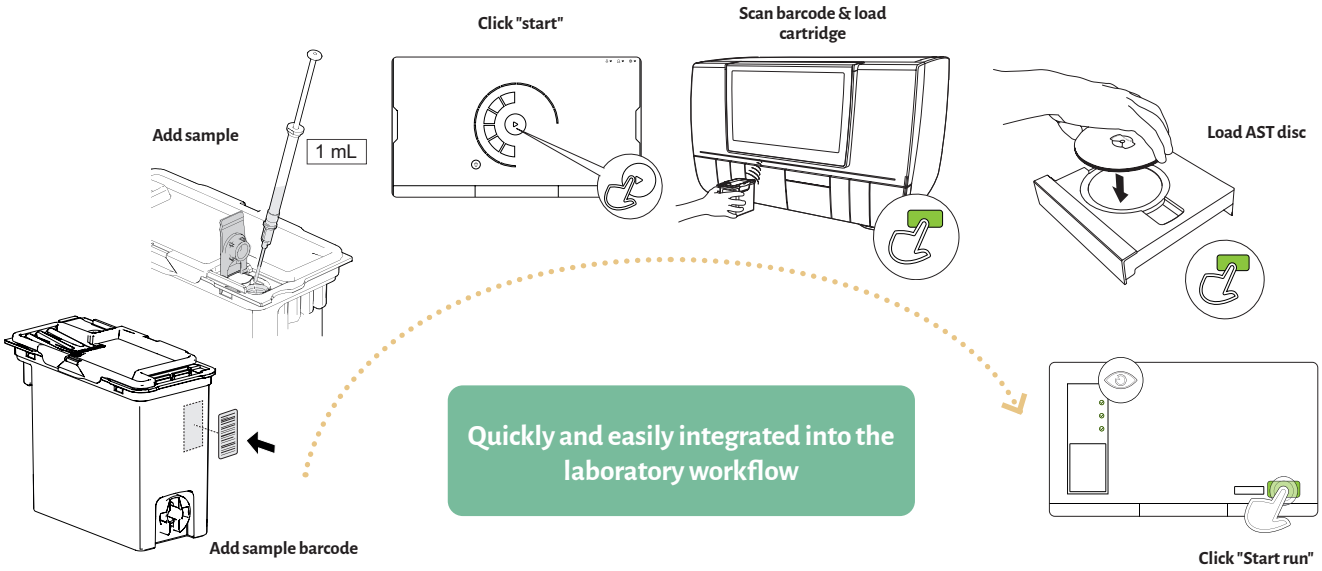
The cartridge contains all reagents and disposable articles needed for sample preparation, concentration determination, dilution and growth medium adaptation.

The AST disc

The AST disc is used for concentration determination and susceptibility testing. It contains more than 330 culturing chambers, allowing for a comprehensive antibiotic panel with many two-fold dilution steps for each antibiotic. Susceptibility testing from a broader panel gives a more complete result and reduces the need for further time-consuming tests.



Anyone in the lab can start ASTar, anytime



Add positive blood culture and load consumables

The user transfers the blood sample from the blood culture bottle to a position in the sample preparation cartridge, scans the patient barcode on the cartridge and places the cartridge and the AST disc/panel in the instrument. All steps take place automatically from that point.

Fully automated sample preparation and susceptibility testing

The instrument's ability to handle different organisms simultaneously saves time and allows analysis without knowing the bacterial ID. The AST disc, loaded with bacteria and antibiotics, is placed in a temperature-controlled part of the instrument. The culture chambers are read by an optical detection system, and an image analysis algorithm quantifies the bacterial biomass over time. MIC is determined using an algorithm that also takes the bacterial ID into account, and the bacteria is classified as susceptible (S), susceptible, increased exposure (I) or resistant (R)

ASTar System FDA cleared in 2024

In April 2024, Q-linea announced that the ASTar Instrument and ASTar BC G- Consumable Kit had been granted 510(k) market clearance by the U.S. Food and Drug Administration (FDA). The FDA categorises clinical laboratory tests by their complexity based on seven criteria in the CLIA regulations. The criteria focus of personnel and laboratory processes, for example, level of automation aof the operational steps. The majority of FDA cleared rapid AST systems are categorised as high complexity. ASTar is categorised as a moderate complexity system.

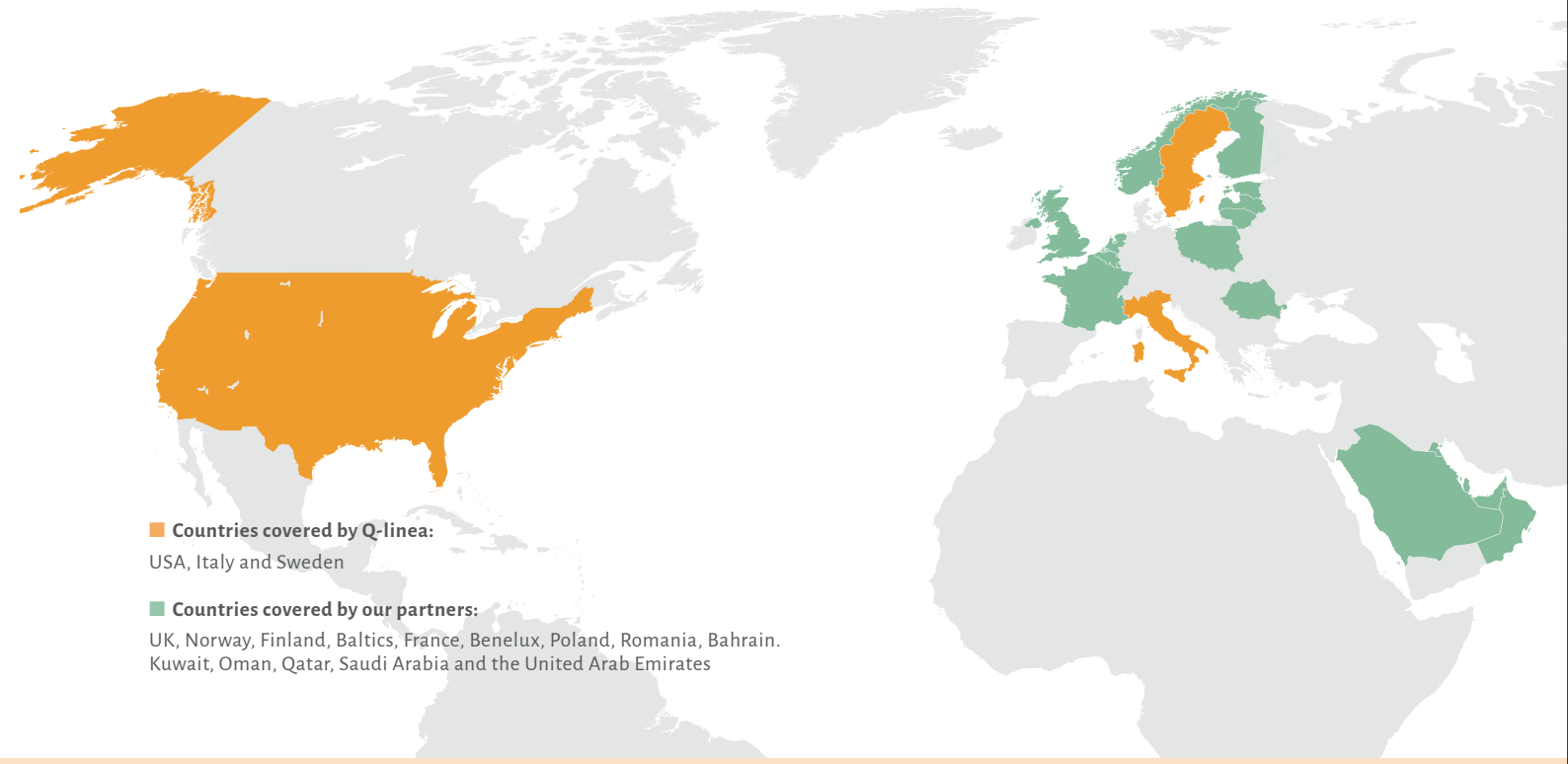
ASTar Instrument and ASTar BC G- Kit (consumables and analysis software) were first CE-marked according to the directive 98/79/EC for in-vitro diagnostic medical devices in May 2021. Q-linea implemented all applicable IVDR requirements and CE-marked ASTar instrument according to IVDR in May 2022. ASTar BC G- Kit was CE-IVDR marked in 2023. The certification was issued by Q-linea's notified body TÜV SÜD.

Q-linea's expansion into the world market

Our first commercial placement of ASTar in 2024 came from Italy. An ASTar system was installed at the Policlinico Tor Vergata University of Rome. The company continued the geographical expansion with a focus on countries and regions that are actively working to address the challenge of antibiotic resistance. As a result, we partnered with Mecro System in Romania and the AMICO Group in the Middle East.

Romania is one of the countries with the highest number of infections with antibiotic-resistant bacteria in EU. According to the European Centre for Disease Prevention and Control (ECDC), the high rate of antibiotic consumption and the widespread use of last-line broad-spectrum antibiotics is particularly worrying[1]. The country is now implementing a national strategy plan for the prevention and limitation of healthcare-associated infections and combating antibiotic resistance. Similarly, the GCC countries have developed a joint strategic AMR plan[2], where one of the elements is ensuring access to microbial identification and antimicrobial susceptibility tests, and the timely and relevant reporting of results.

In April 2024, Q-linea announced that ASTar instrument and ASTar BC G- Consumable Kit had been granted 510(k) market clearance by the U.S. Food and Drug Administration (FDA). According to the Centers for Disease Control and Prevention, at least 1.7 million adults in the United States develop sepsis each year and nearly 270,000 die as a result. Several ASTar evaluations had been started prior to the approval and performance and results were as expected in line with what had previously been shown in several European studies.



Countries covered by Q-linea:
USA, Italy and Sweden

Countries covered by our partners:
UK, Norway, Finland, Baltics, France, Benelux, Poland, Romania, Bahrain. Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates

The only rapid AST system granted New Technology Add-on Payment (NTAP)

The US Centers for Medicare & Medicaid Services (CMS) offers manufacturers the ability to apply for an NTAP code, providing additional payment to hospitals above the standard Medicare Severity Diagnosis-Related Group (MS-DRG) payment amount.

In August 2024, CMS announced that ASTar System had been awarded NTAP funding. The NTAP reimbursement will be available to US hospitals for Medicare patients in the amount of USD 97.50 per eligible patient. The funding will be effective for three years, from October 2024 through September 2027. Cases involving the use of the ASTar system that are eligible for NTAP will be identified by a unique code.

“I do believe that ASTar has a high potential to positively impact clinical care”

Rebecca Yee, PhD, D(ABMM), M(ASCP), Chief of Microbiology, Assistant Professor of Pathology, George Washington University, Washington D.C., USA

What was your first encounter with Q-linea and ASTar?

I first encountered Q-linea and ASTar at a scientific conference focused on infectious diseases. It was a fantastic opportunity to see their innovation in action. I was able to meet their knowledgeable team, who provided valuable insights into the technology and its applications, and I even got a hands-on demonstration of the instrument, which showcased its capabilities and ease of use.

You've had some hands-on time evaluating ASTar: Can you tell us a bit about the study?

Our study is to evaluate the performance and clinical impact of ASTar for utility in our hospital in a metropolitan city. We compared the ASTar to our standard of care method which is the MicroScan Walkaway platform. For performance, we compared the rates of categorical and essential agreement between the two platforms and the time to actionable results, as defined as the time from positive blood culture to availability of AST report. To determine the impact that ASTar has on clinical care, our antimicrobials stewardship team, consisting of an infectious disease physician and infectious disease-trained pharmacist, reviewed the AST report generated by ASTar to propose follow-up hypothetical clinical decisions.

How does ASTar differ from your existing systems or routines?

The conventional workflow for positive blood cultures begins with the detection of microbial growth in automated blood culture systems, indicated by a flagged positive bottle. We then perform Gram-stains, subcultures, and run a rapid PCR panel for identification and genotypic susceptibility testing with results within 2 hours. Unlike ASTar, which is a rapid phenotypic test that contains a wide diverse panel of antibiotics, genotypical susceptibility platforms only contain a very limited number of genetic markers for antimicrobial resistance. Antibiotic resistant mechanisms for Gram-negative organisms are complex and as such, we still need to perform conventional phenotypic antimicrobial susceptibility testing which takes another 24 hours after a pure isolated colony is obtained. Another advantage of ASTar is that comprehensive phenotypic susceptibility testing can be performed directly from positive blood culture bottles without the need to isolate pure colonies, a process that can further delay care. We currently do not have rapid phenotypic susceptibility in-house and ASTar has the potential to fill in the gap.

After using ASTar, what are your conclusions?

Our study demonstrated ASTar's excellent performance with essential agreement of >90% for all antimicrobials tested using a panel of diverse Gram-negative organisms including multidrug-resistant organisms. Compared to our existing workflow, ASTar enables results within 11 h from positive blood cultures, which is 36 hours faster. Our preliminary analysis of hypothetical clinical impact revealed that ~90% of the cases would have resulted in antimicrobial change consisting of de-escalation, escalation, route of administration adjustment, target source optimization and dose adjustment. Potential clinical impacts were exposure to fewer antibiotics, fever side effects and decreased length of stay. In all cases, vancomycin, an antibiotic for Gram-positive organisms, was stopped. As a laboratory leader, not only do I care about the performance of new technology but also, the ease-of-use for my laboratory staff. All the lab users agreed that the ASTar system is easy to use with a very simple one-step transfer, simple and clear user interface, and consumables that are reasonably-sized.

Do you believe that ASTar can impact patient outcomes?

It is imperative to promptly initiate patients on appropriate empirical antimicrobial therapy, as prolonged delays in receiving adequate therapy have been shown to correlate with higher mortality rates. That said, yes, I do believe that ASTar has high potential to positively impact clinical care. With ASTar's rapid turnaround time, clinicians will be able to receive a full antibiotic susceptibility report at least a day earlier than traditional methods. ASTar can then improve antimicrobial stewardship and decrease the time to optimal therapy in the form of escalation or de-escalation of antibiotics. Patients may also lower their risk of side effects from treatment of broad-spectrum antibiotics or empiric therapy. Implementation of ASTar also has the potential to lower healthcare costs by decreasing the length of hospital stay.

“Partnership with Q-linea aligns exactly with AMICO's IVD commitment to deliver impactful technology to the health-care market, specifically to sepsis management teams”

Sherif Harydi, Business Development Director, AMICO Group

Can you tell us about AMICO Group?

AMICO is a leading regional healthcare commercial corporation and IVD distributor with a strong presence across the entire Middle East region – 13 countries, so far. The company has been in the region for decades now – more than forty years – and AMICO has been dedicated to bringing innovation and diagnostic solutions to healthcare providers, enabling them to deliver exceptional patient care. Our mission, specifically in In vitro diagnostics (IVD), is to bridge the gap between cutting-edge technologies and the diverse need for healthcare systems in the Middle East region.

How did you first encounter Q-linea and the ASTar System?

I personally first learned about Q-linea and the ASTar System through my continuous search for innovations that address the critical gap in diagnostics and patient management, specifically for sepsis. Sepsis is always high on the radar for ID doctors and clinical microbiologists, and having sepsis solutions like ASTar is going to change the whole patient management scenario in their hospitals. The real potential of ASTar is to significantly improve antimicrobial stewardship and accelerate targeted therapies, and this is how it caught my attention. Partnership with Q-linea aligns exactly with AMICO's IVD commitment to deliver impactful technology to the healthcare market, specifically to sepsis management teams.

What are your plans for introducing ASTar in the Middle East?

Our work has a three-phased approach. The first phase is to build awareness and educate healthcare professionals about the benefits of rapid AST and its role in patient care and combating Antimicrobial Resistance (AMR). The second phase is to promote adoption by identifying key leadership hospitals and reference laboratories and showcasing to them ASTar's capabilities through pilot programs and partnerships. Lastly, we will push market expansion by collaborating with big institutions, governmental bodies and the private sector to integrate ASTar into their AMR programs and action plans. This will ensure the delivery of precise and rapid AST and make it available across the entire region.

What's your view on the necessity of ASTar in the Middle East?

The Middle East in general has significant challenges with AMR. Firstly, because it is a very diverse region with a lot of international travel. For example, in Dubai, we have more than 200 nationalities living and travelling from every direction on the globe. Secondly, significant challenges are driven by the high rates of antimicrobial misuse, limited diagnostics infra-structure, and the growing burden of Healthcare-Associated Infections (HAI). So, the ASTar system will address this urgent need by providing rapid and accurate AST, and this capability can transform how clinicians in the region will approach patient care, enabling timely, targeted therapies and, of course, the ultimate goal of reducing the risk of AMR proliferation.

How do you feel ASTar could help hospitals and patients

ASTar can revolutionise patient care in many ways. If we talk about hospitals, it enhances infection control programs, guides precise antimicrobial prescription, reduces broad-spectrum antibiotic use or misuse, and supports compliance with AMR stewardship programs. We have been hearing about AMR stewardship programs for decades now, but we don't really see their proper implementation or ownership. We think ASTar will be a great help to achieve that. For patients, by delivering rapid results, ASTar can help ensure timely and effective treatment to improve clinical outcomes, minimise complications, and reduce hospital stay. The ASTar System's efficiency and reliability can alleviate the strain on healthcare resources and benefit the overall healthcare system.

Which aspects of rapid AST systems are most valuable for the future? How does ASTar meet these needs?

For me, the answer is simple: any successful diagnostic has an ideal combination of speed, accuracy, and ease of use. The speed, delivering actionable results within a few hours, is going

The real potential of ASTar is to significantly improve antimicrobial stewardship and accelerate targeted therapies, and this is how it caught my attention.

Sherif Harydi,
Business Development Director, AMICO Group

to facilitate early and precise treatment decisions, which is very important. The second element is accuracy, you need to have reliable data and reliable results to drive the antimicrobial therapies. The last is ease of use, you shouldn't need somebody with a PhD to be able to run the test. This all comes together in ASTar – excelling in all these three areas where we can deliver fast and accurate results while still being easy to use.

Thank you for sharing your insights about partnering with Q-linea and selling the ASTar System, is there anything else you would like to add?

We are so excited here, and the team feels the same way. Many colleagues at Q-linea know that we are just starting our IVD journey under the AMICO umbrella, and when we talk about sepsis management tools, advancements, and innovation, we grab the attention of the board of directors here at AMICO. They express their willingness and support for cooperation in that direction, believing that this will bring high value to the whole offering of AMICO, not only the IVD division. We are excited to bring ASTar to the Middle East, knowing the potential and knowing what it can deliver differently in terms of patient care and AMR management. At AMICO, we remain committed to fostering this partnership, and we look forward to collaborating and collaborating with you and all stakeholders to create a successful and healthier future for everyone.

LIFETIMES - a Health Economics study sponsored by Q-linea

The LIFETIMES study is an important part of our clinical strategy to demonstrate ASTar's safety and value in a clinical setting and investigate its health and economic impact during the treatment of Intensive Care Unit (ICU) patients with bloodstream infections and sepsis.

The study focuses on AST for Gram-negative bacteria, including fastidious bacteria, directly from positive blood cultures, and is being conducted at several sites across Italy, a country with a high prevalence of antimicrobial resistance.

We aim to show that ASTar improves Quality-Adjusted Life Years (QALYs) for patients, helps combat antibiotic resistance and improve infection control measures, reduces hospital costs, and streamlines laboratory and clinical workflows. HEOR studies are important in this process, enabling decision-makers to evaluate how implementing a new system can benefit their existing routines and improve patient outcomes[1].

LIFETIMES is a prospective study, meaning clinicians are using ASTar results in a real-world setting to adjust the treatments given to their patients.

In June 2023, we were proud to announce that the first patient had been enrolled in this multi-centre study, and in March 2024, we presented interim results for the first time at the AMCLI congress in Italy.

Preliminary results demonstrated ASTar can reduce the time to optimal antibiotic therapy by over 30 hours, which could potentially improve the quality of patient care and reduce their overall length of stay in the ICU and hospital. Empiric antibiotic therapies could be adjusted sooner, potentially saving costs and preventing the emergence of antimicrobial resistance.

For healthcare professionals, ASTar lessened the burden of laboratory and clinical workflows, streamlining the treatment process and enabling doctors to act sooner and with greater confidence – at least one day earlier when compared to their current methods. The average cost of an ICU patient in the ICU is $32,000[2], and ongoing cost-utility analysis will discern if ASTar can reduce this amount through expedited and improved care and earlier patient discharge. If so, this would generate substantial savings for hospitals.

We will be sharing the full results from this study in a peer-reviewed publication.

Evaluations of ASTar with successful results

Several other external evaluations of ASTar were performed in 2024. Results from these studies were presented at multiple conferences worldwide. This included evaluations at several sites across the US, a key geographic market expected to see widespread adoption of rapid AST technologies in the coming years. In these evaluations, positive blood cultures from septic patients were tested using ASTar, and performance and theoretical patient outcomes were compared to those of the routine AST methods used in each hospital.

In mid-2024, we hosted a webinar on www.360dx.com/, inviting two study sites to share their data.

Recorded presentation from a workshop held at the AMCLI Congress, March 2024

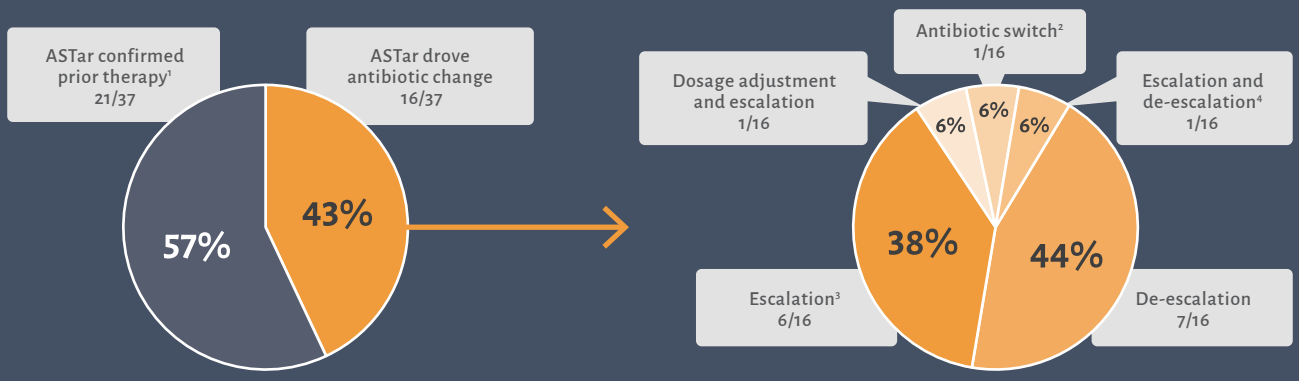
Title: **LIFETIMES – Risultati preliminari di uno studio multcentrico di Health Economics** (English subtitles)

Prof. Maurizio Sanguinetti, Universitá Cattolica del Sacro Cuore, Rome, Italy.

Preliminary results from the LIFETIMES study

In 2024 we presented preliminary data from the LIFETIMES study at multiple congresses worldwide. We are please to share some of this preliminary clinical data here, showcasing how ASTar has already made an impact during BSI patient care.

Clinical impact and treatment changes facilitated by ASTar



1. In three cases the patients died before clinican could act upon ASTar results

2. Due to anaphylactic shock to empiric therapy
3. In one case, ASTar outperformed genotypic results (AmpC)
4. De-escalation of Pip-tazo to Cefepime, escalation by addition of Gentamicin

What do these changes mean for clinicians and patients?

Sooner confirmation of prior therapy

Initial therapy was confirmed as appropriate for the patient and their infection.

- Earlier AST results save time, money, and resources in the hospital
- Reduces unnecessary antibiotic use and prevents patient complications that could results from prolonged infection or treatment

Escalation

Addition of a new antibiotic or switch to a broader-spectrum antibiotic.

- Can prevent resistance due to ineffective treatment, ensuring the patient is cleared of the infection and preserving antibiotic efficacy

De-escalation

Narrowing of antibiotic spectrum or discontinuation of one or more antibiotics.

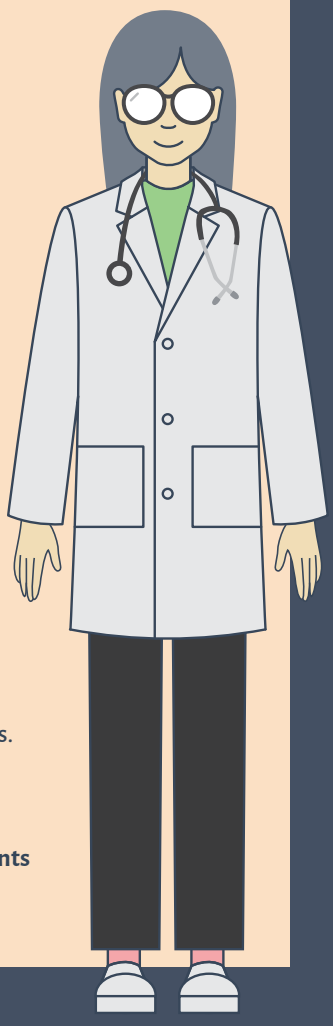
- Minimises exposure to broad-spectrum antibiotics and reduces resistance risk
- Patient is less likely to experience antibiotic toxicity or other adverse events
- Can preserve the efficacy of carbapenems and other high-value antibiotics
- Monetary savings from fewer antibiotics used

Dosage adjustment

Prior antibiotic therapy was correct, but dosage must be adjusted for optimal effectiveness.

- Reduces resistance development or other adverse events in the patient
- Can contribute to lower treatment costs

Sooner appropriate, targeted therapies can lead to faster recovery, benefiting both patients and hospitals, and contributing to improved Antimicrobial Stewardship.



Sustainability is an integral part of Q-linea's vision

Developing tools for improved diagnosis of bacterial infectious diseases, particularly serious illnesses such as sepsis, where incorrect treatment or treatment with effective antibiotics administered too late can have fatal consequences, means working toward a sustainable world. Q-linea's vision is to help ensure that antibiotics continue to be an effective treatment for future generations. This gives sustainability an even broader significance..

In 2024, Q-linea continued its work in the three areas of governance, environmental and social responsibility (ESG). The work was conducted by an interdepartmental group led by the Managing Director Anders Ljunggren.

Corporate governance

An important objective for Q-linea's governance is better documentation of the Company's sub-suppliers. This work continued in 2024, and the processes for this purpose and how suppliers are to be monitored and evaluated are continually being refined. Q-linea has a Supplier Code of Conduct that all its sub-suppliers are expected to comply with. It is available on Q-linea's website.

Environment

Q-linea is adamant about preserving and protecting the environment in all parts of its business. The Company seeks to minimize its direct and indirect negative environmental impact and to continuously lessen its environmental impact by maintaining sound work procedures and using environmentally friendly technology. The company's environmental policy includes an effort to implement and maintain an environmental management system in accordance with ISO 14001 to conduct environmental work in a structured manner. Q-linea has implemented a multi-process environmental management system where most of the requirements of ISO 14001 are covered but has not yet planned any certification of the environmental management system..

The Company's environmental responsibility can be described in the following four areas:

Production

In its own production operations, Q-linea recycles waste and residual products via Ragn- Sells, which is ISO 14001 certified. It also purchases packaging from manufacturers that are ISO 14001 certified.

Q-linea shall:

- ✔ Comply with applicable environmental protection laws and regulations at local, national, and international levels.
- ✔ Engage in safe, resource-efficient and environmentally friendly production and development.
- ✔ Use natural resources effectively. Q-linea currently purchases green electricity, meaning electricity that comes from renewable energy sources.
- ✔ Lower energy consumption and emission of greenhouse gases in every part of the organisation, both during development and manufacturing of components and during future use of the systems.
- ✔ Consider environmental criteria when selecting suppliers.

The product

Q-linea seeks to ensure that all the components in its products are recyclable. However, consumables on users' premises must be regarded as infectious waste and are currently destroyed for the purpose of infectious disease control, primarily through incineration. This also applies to items that have come into contact with antibiotics, which are incinerated to prevent the release of the antibiotics into the environment. However, Q-linea is evaluating alternatives.

Transports

Q-linea shall consider environmental criteria when selecting suppliers and utilise electric transport where possible. Electric trucks have not yet been implemented widely, and Q-linea has chosen carriers that are ISO 14001 certified as its preferred alternative.

Travel

Q-linea shall consider environmental criteria when selecting suppliers and seek to communicate digitally while continuously evaluating various environmentally friendly travel alternatives. During 2024, we continued using digital communication, which gives employees flexibility in where they work when appropriate

Q-linea's overall sustainability goals are set out in the company's vision. This is complemented by important programs and measures for the company's environmental and social responsibility.

with respect to the operation. Q-linea has also continued to utilise the option for employees to participate in large trade fairs and conferences digitally to give more employees the opportunity to engage in continuing education and to stay up to date in their field without needing to travel to these conferences.

Social responsibility

Social responsibility is one of three areas where Q-linea concentrated its sustainability efforts during the year. Q-linea's philosophy is that all employees are equally valuable and should have the same opportunities regardless of individual differences. In fact, Q-linea believes that these differences improve its capacity to develop and change and are an asset to the organisation. The Company's diversity efforts focus on eliminating discrimination and instead valuing and cultivating diversity. Two of the six members of Q-linea's Board of Directors are women, including the Chairperson. Q-linea continually reviews its processes to ensure that they function properly in terms of taking diversity into consideration when hiring employees and consultants. In 2024, Q-linea implemented initiatives to make the development of existing employees more structured and active.

Some important objectives are to:

- ✔ Achieve a high level of dedication to the Company's operations and vision.
- ✔ Be an attractive employer for current and future employees.
- ✔ Support diversity.
- ✔ Offer environmental training courses when relevant.

Interaction with academia is an important part of Q-linea's social responsibility. Q-linea interacts a great deal with Uppsala University. In recent years, the company has received students who have completed their education at Q-linea with a degree project. In addition, Q-linea regularly receives study visits from the university's undergraduate and postgraduate programs.

The Q-linea share

Q-linea AB (publ) is a Swedish public limited liability company whose share has been listed on Nasdaq Stockholm since 7 December 2018.

Market capitalisation and trading

The Q-linea share has been listed on Nasdaq Stockholm since 7 December 2018. The Company's market capitalisation at year-end amounted to SEK 434 million (434). The share is part of the Small Cap segment. The Company is classified as a health - care company. The listing enables the Company to execute its long-term strategy by broadening its ownership base, thereby contributing to increased awareness of the Company and its operations and creating access to the Swedish and international capital markets.

Share capital and number of shares

The Company's share capital at year-end amounted to SEK 5,858,318.60 (5,858,318.60), distributed between 117,166,372 (117,166,372) shares. Of the total of 117,166,372 shares outstanding at year-end, 328,472 were treasury shares. Each share carries one vote per share and the quotient value per share is SEK 0.05.

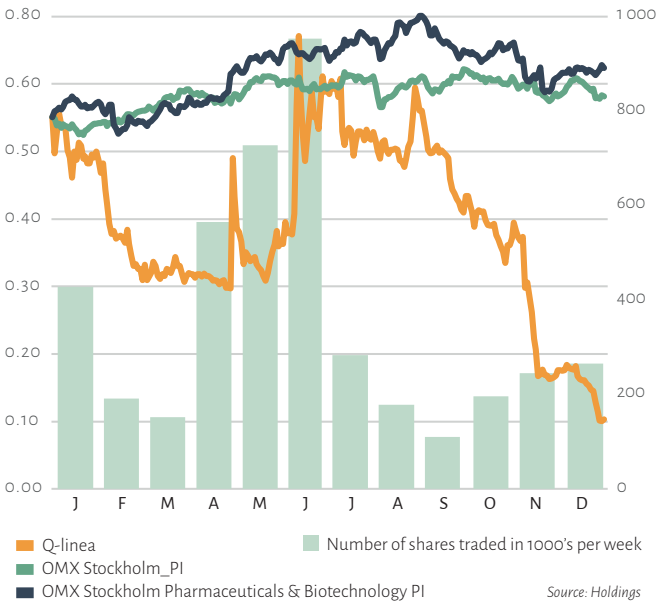
Share capital trend

	Number of shares, thousand	Share capital, SEK thousand
Opening balance at 1 January 2023	**29 538**	**1 477**
Rights issue in July 2023	87 628	4 381
Closing balance 31 December 2023	**117 166**	**5 858**
Opening balance at 1 January 2024	117 166	5 858
Closing balance 31 december 2024	**117 166**	**5 858**

Share turnover

In 2024, a total of 621.1 million (65.9) shares were traded at a value of SEK 273 million (341). An average of 2,474,634 (263,543) Q-linea shares were traded each day.

Share price trend and turnover



Shareholder information

Q-linea communicates with its shareholders and the public through several channels. Information disclosed through press releases, interim reports and annual reports is published on the Company's website: www.qlinea.com. Material from presentations of interim reports can also be downloaded from the website by journalists, investors, analysts and other stakeholders. Q-linea's website is the primary channel for the annual report and copies will not be sent to shareholders unless expressly requested.

Shareholders at 31 December 2024[1)]

	Number of shares	Number of shares and votes
Nexttobe AB	62,712,440	53.52%
Fjärde AP-fonden	8,721,770	7.44%
Investment AB Öresund	7,603,922	6.49%
Nordnet Pensionsförsäkring	5,477,538	4.68%
Ulf Landegren	1,703,004	1.45%
Mats Nilsson	1,030,654	0.88%
Avanza Pension	778,519	0.66%
SEB-Stiftelsen	715,000	0.61%
Handelsbanken Fonder	680,029	0.58%
Aktie Ansvar Sverige	675,000	0.58%
SEB Investment Management	601,720	0.51%
Hans Malm	568,000	0.48%
Cancerfonden - Riksföreningen Mot Cancer	566,699	0.48%
Thorvald Hall	550,066	0.47%
Daniel Redén	504,716	0.43%
Jonas Jarvius	485,857	0.41%
Johan Stenberg	473,509	0.40%
Guntis Brands	470,007	0.40%
Christian Lindström	426,570	0.36%
FCG Fonder	399,453	0.34%
Holdings, 20 largest shareholders	**95,144,473**	**81.20%**
Other shareholders	22,021,899	18.80%
Total number of shares	**117,166,372**	**100%**

[1)] Ownership may refer to personal ownership or ownership through a company.
Source: Monitor

Financial objectives

Until the establishment of ASTar in the US and European markets, Q-linea's objective will be for the Company to be in a strong financial position in order to ensure that its product development and launch programmes and its expansion of production can proceed according to plan. Q-linea will continue to focus on the launch of ASTar.

Dividends and dividend policy

Available financial resources are reinvested in the operations to finance the Company's short-term and long-term strategies. The Board's intention is thus not to propose the payment of any dividends to shareholders before Q-linea generates long-term sustainable profitability.

Any future dividends and their amount will be determined based on the Company's long-term growth, earnings trend and capital requirements, taking into account targets and strategies applicable at any time. Any dividends proposed are to be carefully considered against the targets, scope and risk of the operations..

Share-based incentive programmes

At the end of 2024, Q-linea had two share-based incentive programmes in the form of employee share option programmes. One performance-based incentive programme (LTIP 2021) ended towards the end of the year and the performance share rights expired since the performance targets were not met. These programmes are described in detail in the Corporate Governance Report, in the section "Share-based incentive programmes" on pages 48–50 as well as in Note 9.

Analysts

These analysts regularly follow Q-linea's performance:

ABG Sundal Collier

- **Sten Gustafsson:** sten.gustafsson@abgsc.se

Redeye

- **Johan Unnerus:** johan.unnerus@redeye.se

Board of Directors' Report and financial statements

Translation of the Swedish annual report will be published May 22, 2025 at www.qlinea.com