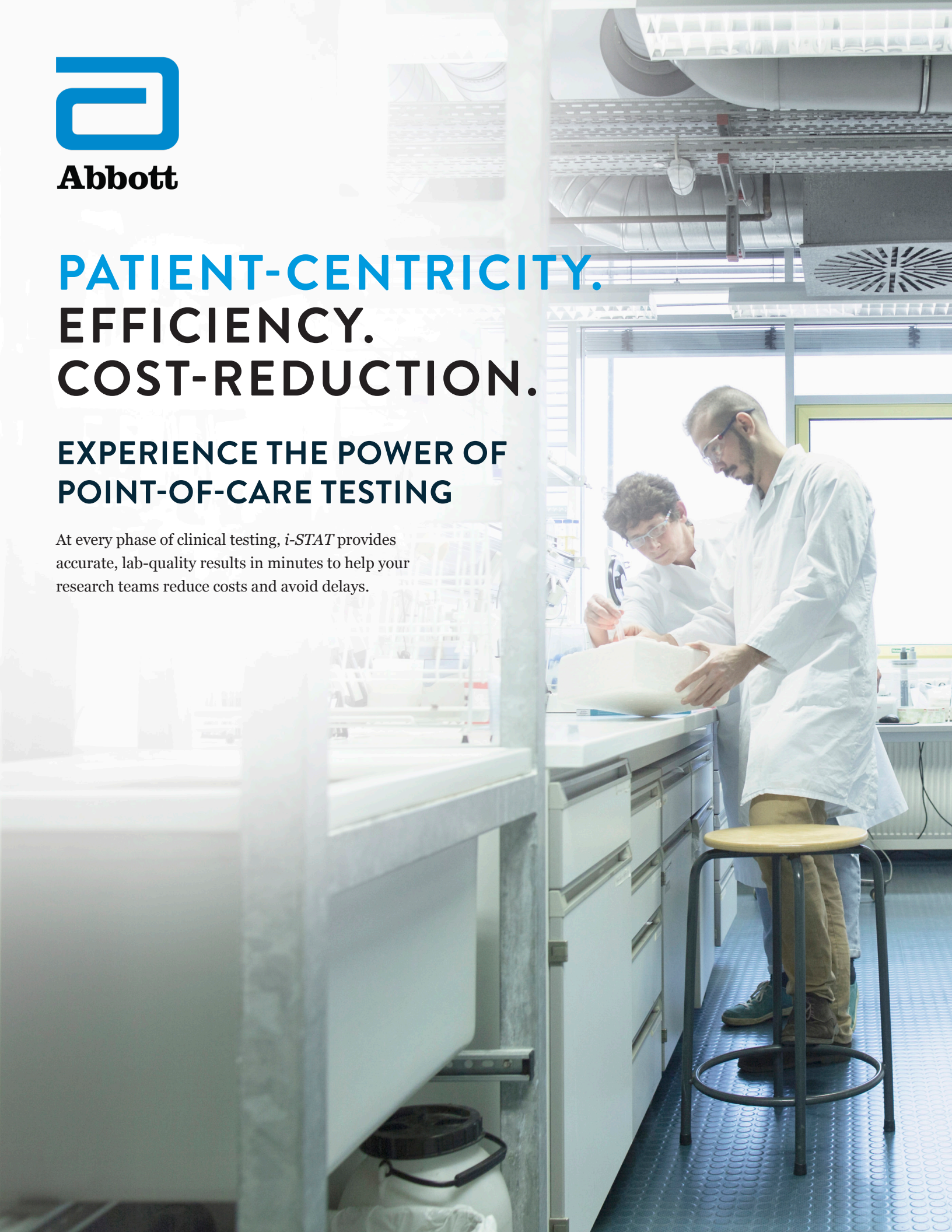
Abbott

PATIENT-CENTRICITY.
EFFICIENCY.
COST-REDUCTION.

EXPERIENCE THE POWER OF POINT-OF-CARE TESTING

At every phase of clinical testing, *i-STAT* provides accurate, lab-quality results in minutes to help your research teams reduce costs and avoid delays.



WHAT IS POINT-OF-CARE TESTING?

Point-of-care (POC) testing refers to laboratory diagnostic testing that is provided in or near the same facility as the patient. POC testing produces rapid test results, avoiding the need to transport samples to a central laboratory for processing and enabling screening or treatment decisions to be made at the time of the patient visit.

In this paper, we will explore how adding POC testing to your clinical trial design can help overcome critical challenges in clinical trial management to enhance patient-centricity, increase efficiency, and help reduce costs.

i-STAT IN ACTION

Interested in learning how major biopharmaceutical companies are gaining the advantages of *i-STAT* in clinical trials?

Find sponsor spotlights on pages:

To efficiently develop new and breakthrough therapies that can help patients around the world, clinical trial sponsors face a variety of challenges that can drastically impact costs, timelines, and the participants themselves. To drive care forward more effectively, make sure your next clinical trial is built to recognize the most significant obstacles in the road and **navigate a more efficient path to success.**

LIMITED PARTICIPATION AND LACK OF DIVERSITY

Evidence suggests that fewer than 3% of all eligible patients participate in clinical trials.[1] A significant limiting factor may be the logistical challenges of trial participation for patients, including lengthy travel times and compliance challenges when multiple site visits are required.

Additionally, diversity remains a significant issue when it comes to most clinical trials, with White patients accounting for approximately 3 in 4 participants globally.[2] This lack of representation in study data limits clinicians' ability to understand safety and efficacy in population sub-groups. For example, Black Americans are twice as likely as White Americans to die from multiple myeloma, yet only 5% of clinical trial participants are Black.[3]

These enrollment issues have significant bearing on the success of a trial. Beyond creating delays, enrollment issues are the single highest reason for trial termination, according to an analysis of terminated trials within the Clinical Trials Database.[4]

An estimated 70% of potential clinical trial participants live more than 2 hours away from a study center.[5]

Guidance published by the Food and Drug Administration in April 2022 stated that clinical trial sponsors have a responsibility to improve their efforts to recruit and enroll members of underrepresented populations.[6]

DELAYS

For trial sponsors, maintaining the trial timeline is often a monumental challenge, and in this regard, the statistics are staggering.

For the trial sponsor, these delays create significant financial hardships by delaying sales and causing potential losses of $600,000 to as high as $8 million per day.[7] For patients, these delays mean they must wait longer for potentially time-sensitive or life-saving therapies.

More than 4 in 5 clinical trials experience delays, with 94% of trials delayed more than a month.[8]

HIGH COSTS AND WASTED RESOURCES

Clinical trials can cost tens of millions of dollars or more, depending on trial size and complexity. For trial sponsors, identifying opportunities to reduce costs by avoiding delays, streamlining the trial logistics, and avoiding risk is critical.

In an interview with the publication Pharmafocus, a senior clinical operations manager at AbbVie reinforced that "The biggest contributor to rising costs is the time it takes to complete our trials—the longer the trial, the higher the cost."[7] Trial complexity is also a noted factor in driving trial costs. According to a study by Tufts research, each additional patient site visit required in the trial protocol added a median of $2 million to the overall estimated trial cost.[10]

Logistical costs, such as preparation and transportation of samples, international shipping permits, and temperature control measures can also add up quickly, and samples that are lost or compromised can result in costly delays or invalid data points.

9 out of 10 trials ultimately double their original timeline in order to meet enrollment goals.[9]

Between 2% and 3% of samples are improperly stored or damaged in transport to a central lab, rendering results invalid.[11] Replacing one lost laboratory sample can cost $712.[12]

HARNESS THE POWER OF POINT-OF-CARE TESTING

POC testing is rapidly gaining traction in clinical trials due to its speed, portability, convenience, and ease of use, as well as its ability to be used across a variety of care settings.

SPONSOR SPOTLIGHT PHASE 1|2|3 GLOBAL PARTICIPANTS 18+ *i-STAT* CARTRIDGE Crea

PFIZER‡ AND BIONTECH‡

COVID-19 + PROJECT LIGHT SPEED[13]

In March of 2020, Pfizer's "Project Light Speed" was tasked with the goal of making the impossible possible: developing medicines to help fight the COVID-19 pandemic before the end of the year.

Pfizer has long been focused on getting new medicines to market faster, reducing timelines and keeping patients at the center of everything.

In 2020, at the start of the COVID-19 global pandemic, the company teamed with BioNTech to take on the most ambitious drug development program in history, an initiative series of clinical trials they called "Project Light Speed."

To expedite screening processes, "Project Light Speed" turned to *i-STAT*® to provide point-of-care testing for 4 studies focused on the oral antiviral medication, Paxlovid* at trial sites around the world.

NCT05438602 **NCT05261139**
NCT05567952 **NCT05386472**

BEING COURAGEOUS, DEVISING UNORTHODOX SOLUTIONS, MAKING BOLD MOVES

By accessing results on-site in minutes, Pfizer and BioNTech accelerated timelines and streamlined processes across every aspect of development–helping to establish their leadership at the forefront of COVID vaccine and antiviral development.

INCREASE PARTICIPATION AND DIVERSITY WITH A PATIENT-CENTRIC APPROACH

POC testing reduces obstacles for patients and providers, potentially leading to accelerated trial enrollment, increased participation, and fewer compliance obstacles.

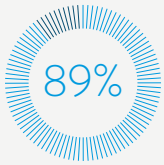
With a more patient-centric approach that incorporates POC testing, visits don't have to take place at traditional clinical sites. Instead, community clinics, mobile nursing care providers, and telemedicine and telehealth providers can utilize the POC model to reach patients closer to where they are. By delivering testing directly at the point of care, trial sponsors can expand the geographic footprint of a traditional trial. This can help drive faster enrollment, greater retention, and enhanced patient representation, accommodating a wide spectrum of patient and sponsor needs.

PATIENT-CENTRIC TRIAL DESIGNS HAVE BEEN SHOWN TO PROVIDE BENEFITS SUCH AS:

3X GREATER DIVERSITY[14]

- Data from decentralized trials has shown up to 3 times greater patient enrollment when compared to traditional models, and with over 3 times the monthly recruitment rate[14]
- Faster enrollment correlates with faster study completion, and may be associated with fewer dropouts, better statistical power, and increased confidence in results[15]

360% HIGHER RECRUITMENT RATE[14]



89% STUDY COMPLETION[14]

POC testing enables expanded use in remote areas or areas without traditional clinical sites. It also allows patients to avoid separate lab visits, minimizing the need for travel and schedule management.

SPONSOR SPOTLIGHT PHASE 2 AFRICA, ASIA PARTICIPANTS PICCOLO ROTORS Hepatic MetLac 12

NOVARTIS‡

TAKING ON PEDIATRIC MALARIA IN AFRICA[16]

Addressing global health crises and challenges and providing patients with more access to care means meeting patients where they are—with Point-of-Care Testing.

A leading developer of antimalarial treatments, Novartis has delivered 1 billion courses of antimalarial treatment, including 430 million pediatric treatments since 1999.

Continuing their leadership, Novartis is developing a novel antimalarial compound KAE609, with financial support from the Wellcome Trust and in collaboration with the PAMAfrica Consortium supported by EDCTP and led by Medicines for Malaria Venture (MMV). KAE609 (cipargamin) has demonstrated rapid clearance of parasites pre-clinically and in patients.

NCT04675931 | To Evaluate Efficacy, Safety, Tolerability and PK of Intravenous Cipargamin in Participants With Severe Plasmodium Falciparum Malaria Reaching remote care sites

Relying on Abbott's POC testing has enabled Novartis to establish clinical trial sites in multiple areas affected by malaria.

Because the systems require minimal provider training or infrastructure and can obtain results with a small sample size (often important for pediatric applications), Abbott POC testing systems offer an optimal solution to support remote care sites across the continent.

ENHANCE EFFICIENCY. AVOID DELAYS.

Accelerate key decisions at every step with POC testing, the time-saving addition to your clinical trial toolkit.

In clinical trials, just as in clinical care, faster answers empower faster decisions. When screening patients or titrating dosages during a trial, the availability of lab results at the point of care can significantly impact the overall efficiency of the trial. A delay of many hours or days between sample acquisition and result generation adds complexity and may require additional patient visits—increasing costs and threatening patient compliance.[10] By utilizing POC testing, trial sponsors can accelerate decisions around screening, enrollment, and dosing.

POC TESTING DELIVERS FASTER RESULTS

OBTAIN ANSWERS IN MINUTES

- Rapid results turnaround

IDENTIFY ISSUES WITH SAMPLES WHILE THE PATIENT IS ON-SITE

- Issues that are not identified until receipt by the reference lab results in at least one lost data point, meaning the patient's data could then be considered incomplete and excluded from the trial entirely

MAKE DECISIONS AT THE TIME OF TESTING

- Eligibility confirmation provided during screening appointment
- Treatment decisions/dosing changes made in a single visit

"By integrating point-of-care testing with *i-STAT*, the trial sponsor was able to reduce screening failures by 50%"

Clinical Trial Solutions Executive

REDUCE RISK. MINIMIZE COST.

Avoid issues associated with mishandling, sample instability, and shipping logistics by adding POC testing to your diagnostic testing armamentarium.

Accelerating enrollment and enhancing compliance and retention offers some of the most impactful opportunities to reduce the overall costs of a clinical trial; however, the potential of POC testing to reduce financial burdens extends even further.

Trials relying exclusively on traditional lab testing often face various logistical challenges, including the proper preparation and transportation of samples and global standardization of results across regional labs. POC testing systems enable each trial site to perform the tests with identical instrumentation and reagents across centers, allowing direct comparisons and statistical analyses across different facilities.

SPONSOR SPOTLIGHT

PHASE 3 | GLOBAL | PARTICIPANTS 18+ | *i-STAT* CARTRIDGE Crea

ASTRAZENECA‡

i-STAT RESULTS INFORM DECISIONS AT EVERY STEP[17]

Robust integration of *i-STAT* POC testing supports patient screening, informs dose titration, and enables inclusion of additional patient results.

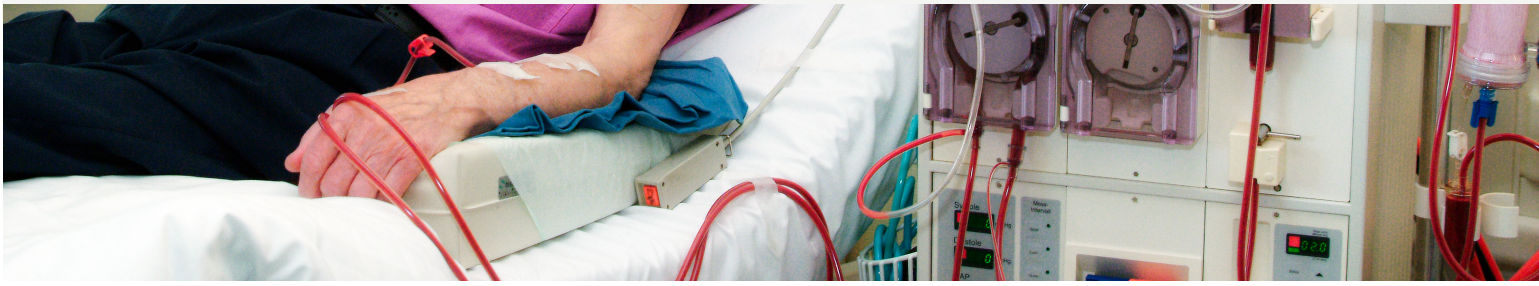
The DIALIZE study was a phase 3b study conducted to evaluate the efficacy and safety of sodium zirconium cyclosilicate (SZC) in the management of hyperkalemia in patients with end-stage renal disease (ESRD) receiving hemodialysis (HD).

NCT04727528 **NCT02163499**
NCT02107092 **NCT03303521**

Study authors noted that *i-STAT* was selected because the system "has been shown to produce accurate, reliable, and robust measurements."

MAKING UP FOR MISSING RESULTS

With the availability of *i-STAT* creatinine test to inform the estimated glomular filtration rate (eGFR) in order to assess kidney health, subjects that had been classified as nonresponders due to missing central lab results were included in a sensitivity analysis and demonstrated results consistent with those from the primary analysis.



FOR DIAGNOSTIC TESTING, GET THE BEST OF BOTH WORLDS WITH i-STAT POINT-OF-CARE TESTING

Adding the advantages of *i-STAT* POC testing to your laboratory testing protocols can help address common problems, such as high rates of screening failures or trouble standardizing results across global samples.

Lab-accurate results allow trial sponsors to make participant inclusion and dosing decisions with confidence.

Simple use minimizes training with easy, intuitive operation across traditional and non-traditional trial settings, even in remote locations.

A comprehensive test menu includes CLIA-waived and non-waived test options to assist with study protocol.

Explore our full menu of cartridges at globalpointofcare.abbott.

Global reach helps protect trial sponsors from roadblocks such as impacts to shipping, lost samples, or limited reference labs.

CMS.GOV

DO YOU NEED CLIA-WAIVED POC TESTING?

Many of the cartridges available for use on the *i-STAT* system may be CLIA-waived, depending on the use model. The following excerpt from the Clinical Laboratory Improvement Amendments (CLIA) page on CMS.gov offers additional clarity:

In most cases, research testing where patient-specific results are reported from the laboratory, and those results will be or could be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" are presumed to be subject to CLIA absent evidence to the contrary.

In cases where patient-specific test results are maintained by a statistical research center for possible use by investigators in which the results are not reported out as patient-specific and could not be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings," CLIA would not apply.[18]

IN YOUR NEXT TRIAL, EXPERIENCE THE POWER OF i-STAT

Utilizing *i-STAT* POC testing can help you increase the number of patients that can be recruited and retained, accelerate timelines, and reduce risks while lowering costs.

PRE-SCREENING AND SCREENING

Eliminate additional visits to increase enrollment rates and support study subject recruitment.

DOSE TITRATION

Maintain therapeutic range and blinded results by both testing and making dosage changes within the same visit.

SAFETY TESTING

Ensure the study subject is in an appropriate state of health to participate.

PEDIATRIC USE

Generate quick test results with reduced blood volume and avoid additional site visits.

TESTING LABILE ANALYTES

Overcome the logistical challenges of transporting highly labile analytes or those with short half-lives to a central lab.

"We are committed to offering our customers a 'white-glove' experience, ensuring that POC testing with *i-STAT* is seamlessly integrated onto their trial protocols."

Senior Manager, Global Accounts (Clinical Trials), Abbott

ACCESS DEDICATED IMPLEMENTATION SERVICES

GUIDANCE and management of the implementation process
TRAINING, including remote and on-demand options, customized to your trials' needs
SUPPORT available 24/7 for technical assistance

PARTNER WITH ABBOTT TO ACCESS ADVANTAGES, INCLUDING:

GLOBAL CAPACITY to support trials in virtually any location
CONTRACT RESEARCH ORGANIZATIONS (CRO) collaboration for seamless integration
SUPPLY CHAIN expertise and prioritization

Talk to an Abbott representative about integrating POC testing into your clinical trial design and learn how *i-STAT*'s ease of use, convenient delivery, and ability to reach wider and more diverse ranges of patients can help accelerate your biopharmaceutical research.

CONTACT YOUR ABBOTT REPRESENTATIVE

AND LEARN MORE ABOUT HOW WE CAN HELP YOU AT WWW.GLOBALPOINTOFCARE.ABBOTT

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