Rapid diagnostic advantages in clinical research

The COVID-19 pandemic demonstrated how lateral flow point-of-care (POC) testing can improve target population enrichment and decrease loss of patients to key analysis sets once confirmatory testing becomes available. Rapid diagnostic tests (RDTs) deliver quick and accurate results, which aid faster decision-making in patient management.[1] Further, these tests enhance patient safety by providing critical information needed to treat specific bacterial infections, helping to reduce antimicrobial resistance.[2]

RDTs also increase the likelihood of enrolling patients with the target pathogen for which the trial is aiming to develop a therapeutic agent. This decreases the use of empiric therapy in patients who are unlikely to benefit, and it provides greater assurance to patients when they consent to trial participation. Fortrea is integrating these POC tests in our strategic proposals for infectious disease trials to drive efficiency, precision and success in clinical research. While much of this technology is available for select indications, obtaining payor coverage remains challenging in routine clinical care.



Patient-centric solutions for clinical trials

Encouraging patient-centric study protocols is one way that Fortrea is advancing its mission to “bring life-changing treatments to patients faster.” Protocols that provide clear benefits to the enrolled patients is a key operational strategy in sepsis treatment trials. Including POC testing in a protocol’s screening procedures can ease the informed consenting process for sites, patients and legal representatives. With expedited test results, physicians can quickly determine whether treatment with an investigational or approved drug is appropriate. This helps overcome a significant recruitment challenge of sepsis treatment trials, where patients are often unconscious and consent must be provided by a legal representative.

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For example, the BIOFIRE® FILMARRAY® TORCH can detect and identify pathogens and susceptibility within 45 minutes to 1 hour. In countries where this POC test is not covered by insurance or national health coverage, patients benefit from faster, more effective treatment compared to the 2-3 days required for standard blood cultures. This accelerated diagnosis offers a significant clinical trial advantage over standard care.

Reducing antimicrobial resistance with rapid diagnostics

Another serious threat to patients with infectious diseases is antibiotic resistance. In acute respiratory infections (i.e., flu), treating physicians are pressed to begin antibiotic treatment before lab cultures confirm the target bacteria. With rapid diagnostics from Cepheid, bacteria can be identified in approximately one hour, allowing for targeted treatments rather than broad-spectrum antibiotics, which may not be effective.

Clinical trial stakeholders also benefit from having quick information in the early stages of screening, as this helps to determine whether a patient is an appropriate candidate for enrollment in a specific arm of the study. This leads to more precise and effective treatment, reduces the chance of developing antimicrobial resistance and leads to shorter hospital stays.[3]

Cost efficiency and study success

As governments and health insurance companies negotiate lower prices for drugs, drug development will be forced to deliver quality clinical trials in a more cost-effective manner. In acute infection trials, patients are typically enrolled based on clinical symptoms because waiting for confirmatory culture results can delay treatment. However, once these confirmatory cultures return, they may not always indicate the presence of the target pathogen(s).

Any patient who is randomized counts in the intention-to-treat (ITT) analysis and safety sets, and if they do not have the target pathogen(s), they are usually excluded from the efficacy analysis set. Incorporating RDTs in a study protocol can increase inclusion in the efficacy analysis set by ensuring that more patients meet the inclusion criteria from the outset. This strategy results in cost savings by reducing the number of patients lost to efficacy analysis, decreasing overall sample size and shortening the study timeline. This is an important part of the work Fortrea is doing to provide our sponsors with strategies that keep them at the forefront of drug development.

Conclusion: the future of rapid diagnostic tests in clinical trials

Integrating rapid diagnostics in infectious disease clinical trials marks an important advancement in research and management. RDTs accelerate the accurate diagnosis of infections, enabling timely and targeted interventions. Furthermore, RDTs can streamline trial processes, facilitate real-time data collection and enhance the overall efficiency of clinical studies.

As we move forward, continued investment in RDT technology and its application in clinical trials will be crucial for addressing the challenges posed by infectious diseases. Ultimately, this will lead to improved public health responses and superior disease management strategies. Fortrea's infectious disease physicians and subject matter experts are partnering with drug development companies to implement these kinds of patient- and site-centric strategies to accelerate treatment discovery and delivery.

With the right CRO, exceptional infectious disease trials are possible.

Contact us today to explore how our tailored solutions can bring your therapies to patients faster.

References

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