STUDYBOX | Empowering Your Research

Diagnostics Done Right

Our focus is 100% IVD.

We don't do drugs.

The Studybox team has **55+ regulatory clearances** through 510(k), Dual Path 510(k) / CLIA Waiver, OTC, and EUA. Additionally, we support studies including Specimen Collection, Biothreat, Reproducibility, Near Cut Off, and Readability.

Reduce Time To Market.

Our CRO model **accelerates clinical studies** by reducing wasteful spending, site overhead, and enabling quicker detection of study anomalies.

From protocol design to regulatory submission, our experts see your project through from conception to completion.

Accelerating IVD Clinical Studies Through Expertise and Accessibility

Focus on your research, not the logistics. Studybox minimizes study complexity and cost by seamlessly integrating everything from supply management to IRB approval. We deliver precision and efficiency, allowing you to accelerate your path to results.

Reduce Study Timelines and Save Money with Studybox's Proprietary Method

- All in one eTMF, EDC, eSource, and eConsent platform with **rapid build time**.
- IVD focused team familiar with nuances and requirements of IVD studies.
- Real time continuous clinical and data monitoring results in **faster database lock and study closeout**.

Exclusive IVD Research Sites

- **Fast site selection and qualification** through the exclusive Studybox IVD site network.
- Prequalified and contracted sites, reference labs, and IRBs **enable faster study start up** and broadens site access.
- Sites support the necessary intended use operators for waived, moderate, and high complexity testing.

Prospective Sample Collection

- New specimen collections can **launch in as little as one week.**
- IRB approved protocol covering most specimen types.
- Eliminates the time and expense of initiating a new study for each collection.
- Data capture customized to your study needs (demographics, concomitant medications, symptom onset, symptom profile, and more).

Studybox Site Locations Nationwide

Over 100 IVD Focused Sites: Leveraging our expertise in IVD studies, we cultivate sites specifically tailored to efficiently conduct IVD research.

Geographically Distinct: Studybox sites are positioned throughout the country to cover FDA requirements and geographic diversity. We reach the underserved and diverse populations for optimized study outcomes.

Diagnostic Studies Done Right.

With deep expertise in IVD studies, we bring a thorough understanding of FDA guidance, offering the knowledge and confidence essential for successful, compliant research partnerships.

Therapeutic Areas Include:

- Infectious Disease
- STD/STI Detection
- Hematology
- Drugs of Abuse
- Antimicrobial Susceptibility (AST)
- Gastrointestinal Health
- Women's Health
- Cardiovascular Disease
- Biothreat

Ready To Partner With Us?

Ready to transform your process from research to results? For a complimentary study consultation, **scan the QR code or contact us directly at:** studyboxresearch.com

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