

CLSI Introduces New Product—Method Navigator—to Help Customers Understand and Meet Regulatory Requirements

CLSI introduces Method Navigator, a comprehensive subscription product to help laboratories identify, understand, and meet regulatory requirements.

MALVERN, PENNSYLVANIA, USA, August 15, 2022 /EINPresswire.com/ -- The Clinical and Laboratory Standards Institute (CLSI) is excited to introduce Method Navigator, a comprehensive subscription resource that helps laboratories identify, understand, and meet regulatory requirements.



Method Navigator is an online tool that provides users with quick and easy access to specific guidance from CLSI documents. The tool was designed to help test developers—whether they are test manufacturers or laboratories developing tests—fulfill FDA, CLIA, ISO, and other requirements. Built off of CLSI document EP19’s “Test Life Phase Model,” the product includes links to requirements, guidance tables, evidence tables, and fillable and downloadable checklists.

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Method Navigator covers all phases of test method establishment, such as feasibility and design, development, and validation.”

Paula Ladwig, MS, MLS(ASCP)

“Method Navigator is CLSI’s new web-based tool created to help both developers and end users meet applicable regulatory and accreditation requirements. The tool pairs test method establishment and implementation with the Quality Management System. Method Navigator covers all

phases of test method establishment, such as feasibility and design, development, and validation,” shared Paula Ladwig, MS, MLS(ASCP), CLSI Chairholder of the Expert Panel for Evaluation Protocols. “For example, by using Method Navigator, a developer can easily find the experimental designs for validation studies along with the documents and records necessary to record and summarize the results. Method Navigator also covers all phases of test method

implementation, including preliminary evaluation, verification, launch, maintenance, and retirement. Method navigator also contains customizable checklists for the laboratory. For example, one checklist helps the lab ensure they're ready for launch. Method Navigator is a helpful tool to ensure you have the documents and records needed to meet requirements for every test method developed and implemented in the clinical laboratory."

Jennifer Rychert, PhD, D(ABMM), Medical Director at ARUP Laboratories and Vice-Chairholder of CLSI Document EP19, A Framework for CLSI Evaluation Protocols noted "Developing, validating, and implementing a test in the clinical laboratory that conforms to all of the regulatory and accreditation requirements can be challenging. Method navigator is a valuable tool that guides the user to all of the relevant requirements and guidance they need to ensure success. It provides access to everything from a simple checklist of the required documentation to a more in depth understanding of risk management."

Method Navigator is available now. For more information, visit clsi.org/method-navigator.

On August 23 at 2 p.m. EDT, CLSI will be hosting a free webinar and demonstration of Method Navigator. Participants will be able to:

- Understand the purpose of CLSI's Method Navigator.
- List the 8 phases of the CLSI Test Life Phases Model.
- Describe how to use Method Navigator when establishing or implementing a new test method.

For more information and to register, visit clsi.org/webinar.

CLSI sets the standard for quality in medical laboratory testing. A not-for-profit membership organization, CLSI brings together the global laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine.□□□

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For over 50 years, our members, volunteers, and customers have made CLSI a respected, transformative leader in the development and implementation of medical laboratory testing standards. Through our unified efforts, we will continue to set and uphold the standards that drive quality test results, enhance patient care delivery, and improve health care around the world.□□□

By using CLSI standards, laboratorians can improve process quality, speed the development of standard operating procedures, and implement safer practices with greater ease and efficiency.

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