The Next Generation Sequencing Quality Initiative: Collaborating on Tools Needed Today

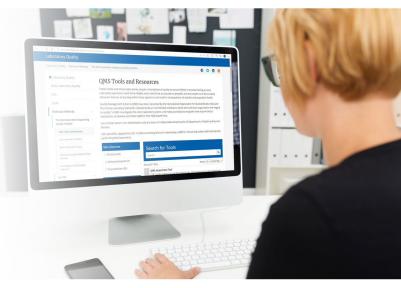
A powerful diagnostic and surveillance tool like next generation sequencing demands an equally powerful quality management system (QMS) to assure consistent, reliable data at any scale. The equipment, material, personnel, and training required to derive and maintain production of high-quality sequencing data requires a significant investment of time and resources. Clinical and public health laboratory (PHL) personnel can find free tools and resources to introduce or strengthen quality management in their workflows, available online from the <u>Next Generation Sequencing (NGS) Quality Initiative</u>.

Find Tools to Use Now and Look Forward to More Resources

The NGS Quality Initiative is a collaboration between CDC, the Association of Public Health Laboratories (APHL), and state and local PHLs that develops and publishes customizable, ready-to-implement guidance documents, standard operating procedures, forms, and tools. These products serve the needs of laboratory professionals,

bioinformaticians, quality managers and supervisors, laboratory managers, epidemiologists, and clinical microbiologists who are interested in NGS data quality or have a role in quality management.

Using these products helps laboratories create or strengthen pre-analytic, analytic, and post-analytic processes to ensure their equipment, materials, and NGS methods produce high-quality results consistent with quality standards. Test developers, laboratory leaders, and other stakeholders can use products from the site to create a suite of customized standard operating procedures to guide high-quality use of NGS technology. Use of these products helps ensure accurate, consistent sequencing results that conform to regulatory requirements, when applicable. All products are aligned with CDC's ongoing quality improvement efforts.



Laboratory staff can download free NGS tools from CDC's website.

Redesigned Web Page and Expanded Catalogue of Resources

To improve accessibility to resources, the Quality Initiative has updated its <u>QMS Tools and Resources web page</u> with search functionality and filters that produce results specific to your laboratory's quality needs. The redesigned web page makes it easier for your laboratory to filter tools and resources by sequencing platform, laboratory role, Quality System Essential (QSE) building block, and your QMS status; or by using a keyword search. In addition, new products are now available to download, including resources for NGS equipment selection, inventory management, and implementation of bioinformatics tools and software.

Tangible Outcomes for Professionals and Public Health Laboratories

Initiative goals include developing new tools and helping members of the laboratory community share resources. Our products complement existing resources and support the development of a laboratory's current QMS or can act as a foundational quality system. Laboratories can adapt these ready-to-implement tools to quickly train personnel, choose and use appropriate protocols and analyses options, and put effective management and process controls in place. This is especially beneficial to laboratories that perform NGS-based tests subject to CLIA regulations and other laboratory accreditation standards.



Hundreds of users have downloaded the NGS Quality Initiative's free, customizable tools and resources.

Poised to Serve Every Day and in Public Health Emergencies

QMSs have been described by the International Organization for Standardization (ISO) and the Clinical & Laboratory Standards Institute (CLSI) as "coordinated activities to direct and control an organization with regard to quality." Robust QMS tools like those created by this Initiative provide the foundation that helps ensure unimpeachable laboratory data used to inform clinical and public health decisions that impact our health and safety.

Increasing The Impact of Our Products

When clinical and public health laboratories use a QMS to ensure high-quality NGS data, they can deliver more accurate and reliable test results, which positively affect prognosis and improves the health of patients and communities. <u>Visit our website</u> to learn more about how the Quality Initiative is developing a QMS for clinical and public health laboratories performing NGS.

Contact Us

Contact the NGS Quality Initiative at <u>NGSQuality@cdc.gov</u> to request information about the project, our products, the process we use for developing resources, or how your laboratory can collaborate.

