MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

SOMATIC REFERENCE SAMPLES (SRS) INITIATIVE

The Somatic Reference Samples (SRS) Initiative is a public-private partnership convened by the Medical Device Innovation Consortium (MDIC) guiding the development of reference samples that can be used to develop and validate Next Generation Sequencing-based cancer diagnostics and support regulatory submissions. Ensuring that oncology patients receive accurate results is imperative. However, lack of agreed upon, well-characterized, community-validated, and data benchmarked reference samples create potential challenges for efficient development of cancer diagnostic tests. Without proven reference samples, there is potential for misinterpreting results.

This initiative is a pilot project, fully funded by industry and philanthropic organizations, to develop, manufacture, and make available an initial set of ten reference samples. The samples will be engineered to contain ten cancer variants and will include validated data sets.

Over and above development and regulatory application, these reference samples and the diagnostic testing they will support, have the potential to improve reimbursement decisions, adoption, and disease management.

SRS Initiative Steering Committee include FDA, NIH, NIST, CDC, diagnostics manufacturers, funding organizations and payors.

Initiative Goals

1. Create a pathway for improved validation and accuracy of next-generation sequencing-based diagnostic tests using authoritatively characterized and validated somatic reference samples for diagnostics.
2. Seek to transform the regulatory review process, possibly obviate steps expediting companion diagnostics and therapeutic development.
3. Build a sustainable model for somatic reference samples and dataset generation.
4. Expand reference sample generation to include other cancer variants/other diseases.

ABOUT MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, NIST, and other agencies, industry, non-profits, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies.

MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.

We are driving faster, safer, and more cost-effective innovation for patient benefit.

LEARN MORE ABOUT MDIC'S SRS INITIATIVE

MDIC Website – SRS Initiative
www.mdic.org/project/cancer-genomic-somatic-reference-samples/

SRS Landscape Analysis Report
www.mdic.org/resource/srs-landscape-analysis-report/

YouTube Video: MDIC Live with Maryellen de Mars
www.youtube.com/watch?v=zz5YOfFJpu4

FDA Website
www.fda.gov/medical-devices/in-vitro-diagnostics/precision-medicine

CONTACT

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