

WELCOME

NIST 2025 Workshop on Rapid Microbial Testing Methods (RMTM)

Opening Remarks

Nancy Lin

April 8, 2025



Housekeeping

- This event is being recorded (with permission from presenters)
 - Slides will be posted on the workshop website
 - Recordings will be posted on the shared Consortium drive (members only) and will be available upon request for workshop attendees
 - This recording could be released to the public through a Freedom of Information Act (FOIA) request
 - Do not discuss or visually present any sensitive (CUI) material
 - Ensure that no inappropriate material or any minors are contained within the background of any recording
- Q&A feature is available to share questions/comments

National Institute of Standards and Technology (NIST)

U.S. Department of Commerce

the National Metrology Institute

“Industry’s National Lab”

non-regulatory agency, partner with industry to address challenges

To promote U.S. innovation and industrial competitiveness by advancing **measurement science, standards, and technology** in ways that enhance economic security and improve our quality of life



New Classes of Therapeutics Need New Microbial Testing Methods

- Advanced therapies include gene therapy, cell therapy, regenerative medicine approaches need to demonstrate **safety** and efficacy to regulatory agencies
 - Includes testing for microbial contamination
 - Traditional USP <71> compendial sterility testing involves culturing in broth for 14+ days
- Rapid release testing is needed
 - Products are often living materials with short shelf-lives
 - Patients are often very ill
 - **14+ days for sterility testing is too long!**

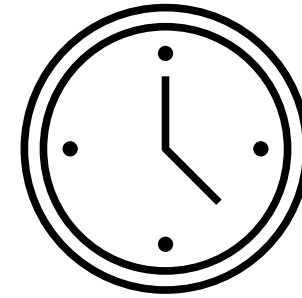
Rapid Microbial Testing Methods (RMTM)

e.g., rapid microbial methods, alternate microbial methods, rapid sterility methods, etc.

Examples

- Respiration (CO₂ detection)
- ATP
- Solid phase cytometry
- Raman/IR spectroscopy
- Mass spectrometry
- PCR
- NGS

Results in <24 h up to 2-7 days



- Rapid methods must be shown non-inferior to compendial methods
- Challenging and time-consuming to validate and adopt RMTMs (no rule book)

Adopting a rapid method represents a **significant risk** that even large, established companies are often unwilling to take on at this time

Why a NIST Consortium?

Why a Consortium?

- The challenge requires a **coordinated response** with significant input from the stakeholder community
- **Lessens risks** being placed on any single entity
- Helps **develop consensus**
- **Leverages subject matter expertise** from the stakeholders

Why NIST?

- **Non-regulatory agency** of the U.S. Department of Commerce,
- **Neutral convener** for industry consortia, standards development organizations, federal laboratories, universities, public workshops, and interlaboratory comparability testing
- **Cross-disciplinary expertise** in engineering and the physical, information, chemical, and biological sciences

NIST RMTM Consortium Overview

Goal

Lower the barrier for adoption of RMTMs in regenerative medicine and advanced therapy products

Approach

Convene stakeholders in the pre-competitive space to **develop measurement solutions and standards** that increase confidence in the use of rapid testing for microbial contaminants



- Launched September 2020
- Free to join
- Stakeholder-driven

NIST RMTM Team



Scott Jackson
Co-Lead



Nancy Lin
Co-Lead



Jason Kralj



Stephanie Servetas



Kirsten Parratt



Tyler Laird



Dawn Henke
SCB Liaison



Joy Dunkers



Sandra Da Silva



Monique Hunter



Tara Eskandari



Sheng Lin-Gibson

Biopharma



Instrument/Reagent Manufacturers



Service Providers



Government



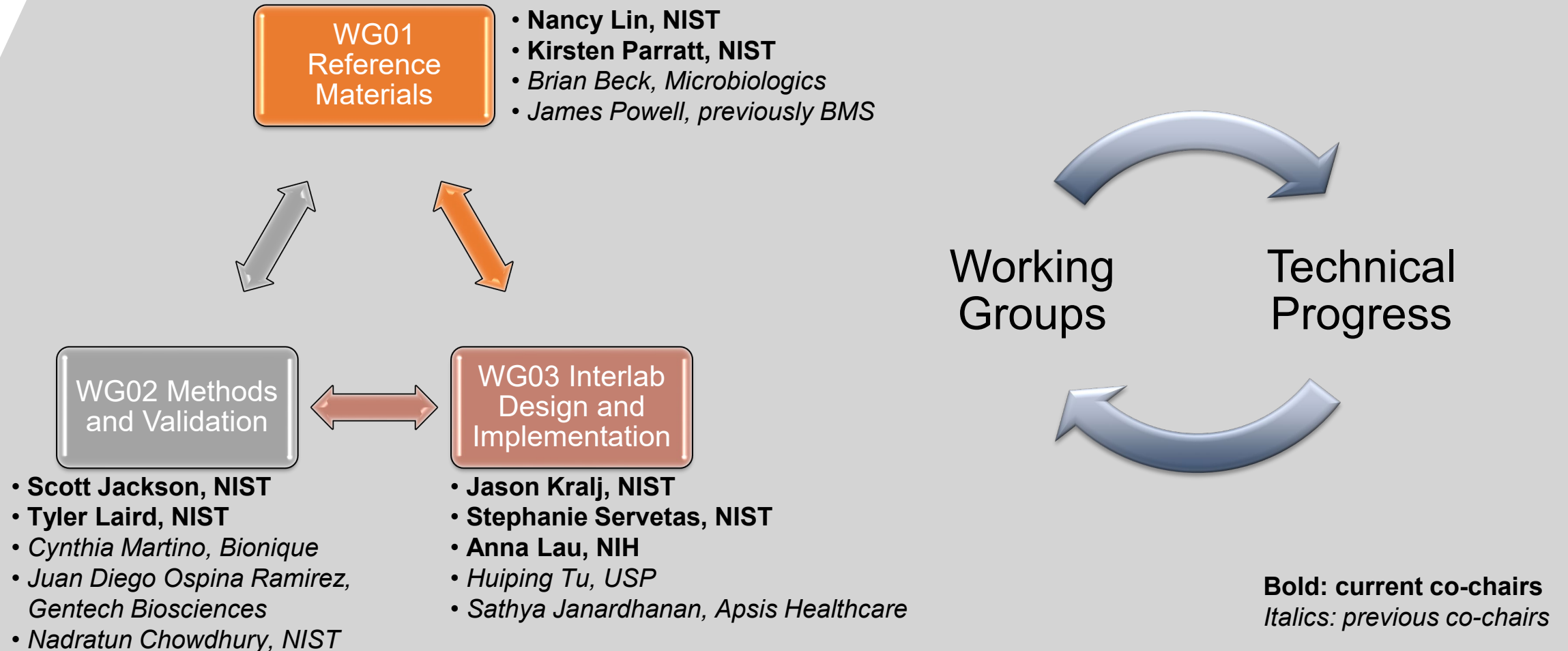
Academia



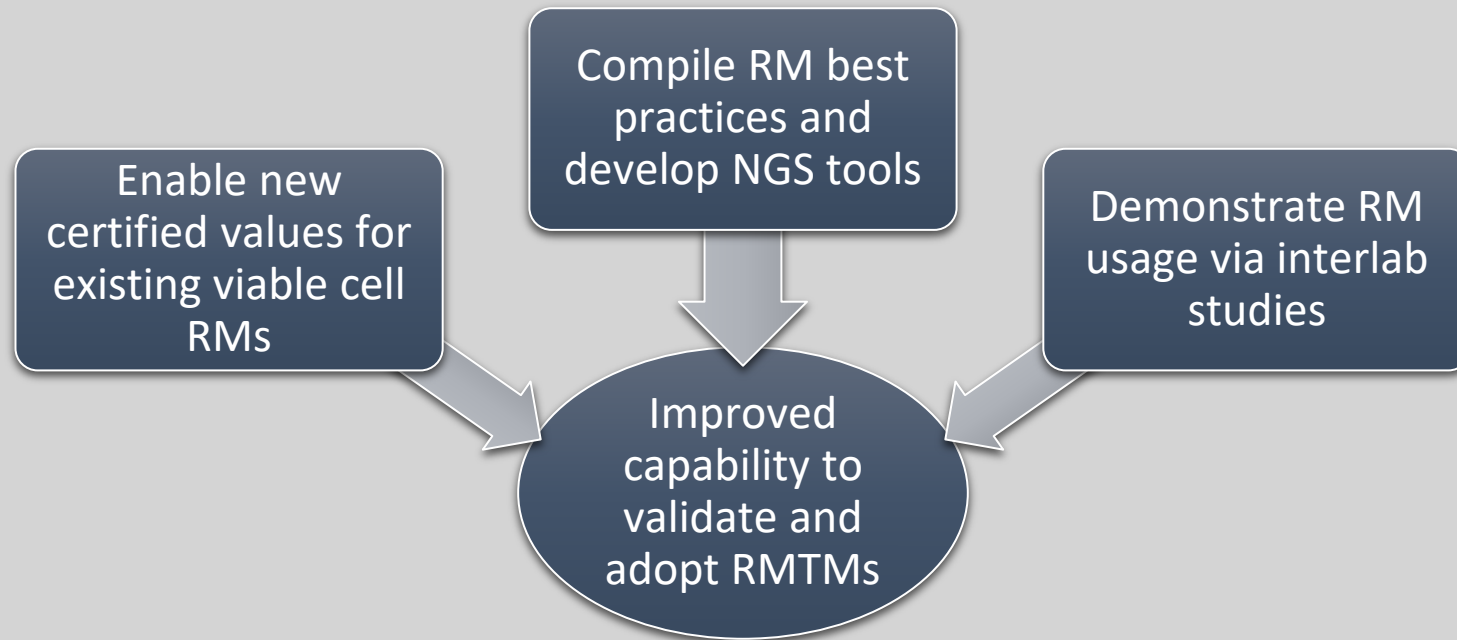
Industry Advocacy Groups



Consortium Organization



Consensus Direction for the Consortium

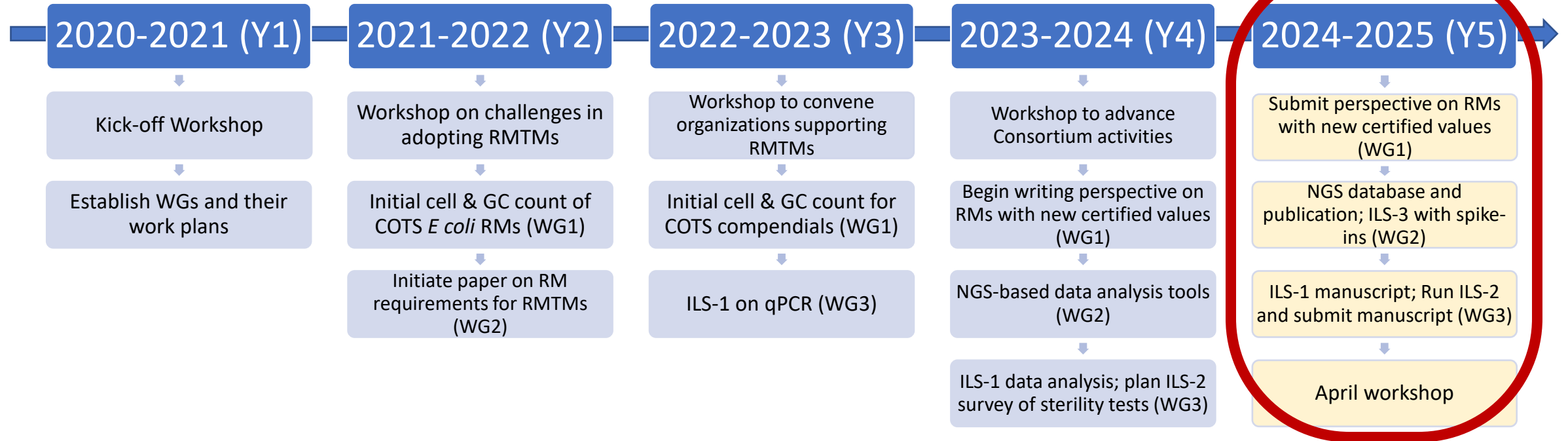


Focus on advancing molecular sterility methods

RMTM Consortium Timeline (Five-Year CRADA)

Start Date:
08/01/2020

End Date:
08/01/2025
(Extending 2 y)



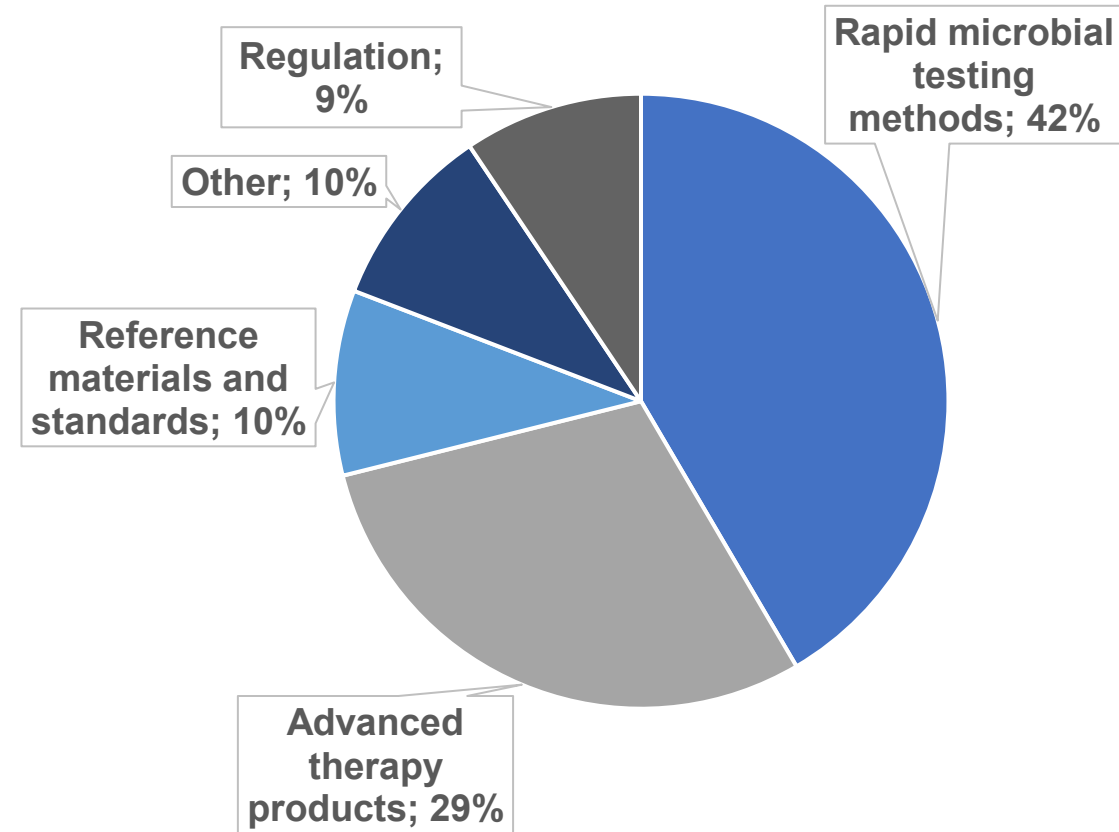
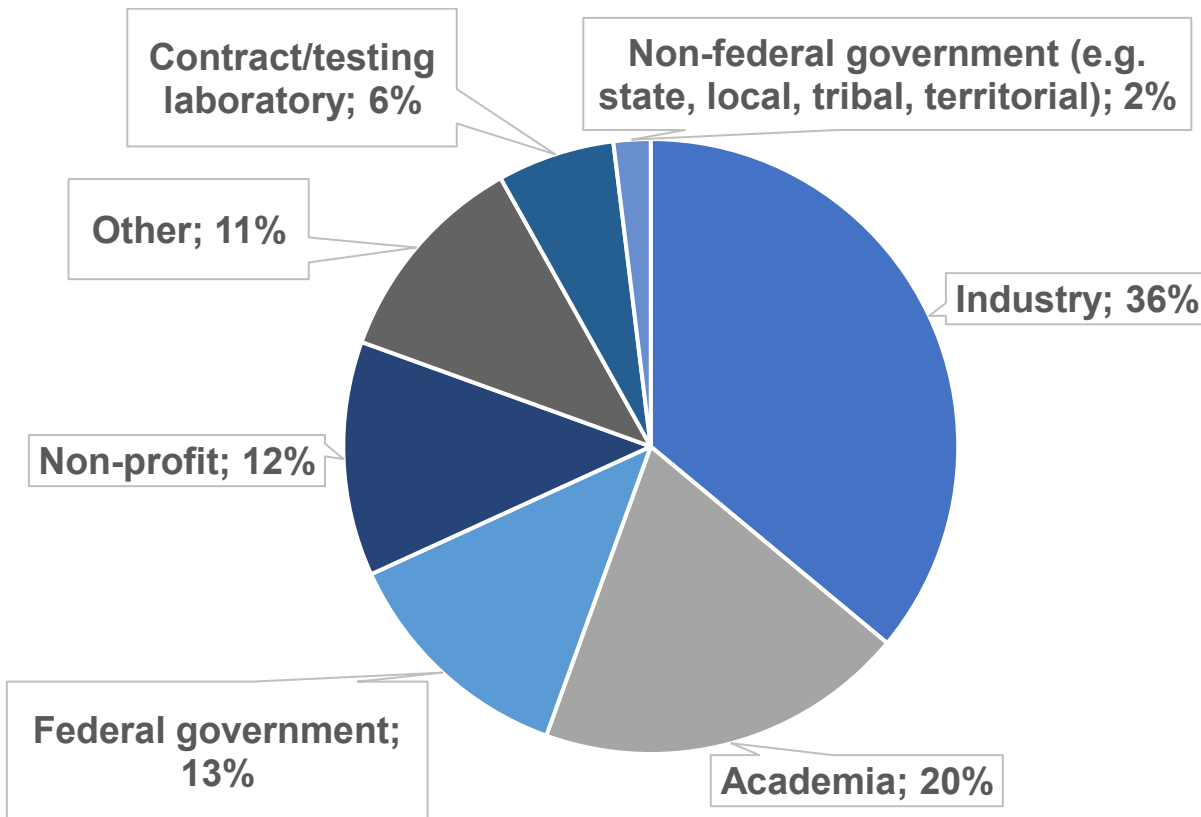
WG – working group
GC – genome copies
COTS – commercial off the shelf
RM – reference material
ILS – interlaboratory study

2025 RMTM Workshop

Goal

- Discuss recent technological advances in the field of rapid sterility testing for advanced therapy products
- Provide an update on the NIST RMTM Consortium activities

Workshop Registrants



n=308

Agenda

Time (ET)	Presentation/Topic
11:00 AM – 11:15 AM	Welcome, Consortium Overview, and Workshop Introduction, <i>Nancy Lin (NIST)</i>
11:15 AM – 12:15 PM	Technical Advances in Rapid Sterility Testing 11:15 AM: Application of Nanopore Long-read Sequencing to Sterility Testing for Cell Therapy Products, <i>James Strutt (Singapore-MIT Alliance for Research & Technology)</i> 11:45 AM: Detection of Pathogens in Complex Matrices via NomadX Platforms, <i>Heidi Leonard (NomadX)</i>
LUNCH (on your own) 12:15 PM – 1:15 PM	
1:15 PM – 1:45 PM	NIST RMTM Consortium WG1 - Reference Materials: Toward Microbial Cell Reference Materials Characterized beyond CFU, <i>Nancy Lin (NIST)/ Kirsten Parratt (NIST)</i>
1:45 PM – 2:45 PM	NIST RMTM Consortium WG3 - Interlaboratory Studies: Microbial Contaminant Detection Across Rapid Sterility Testing Methods - Preliminary Interlaboratory Study Findings, <i>Jason Kralj (NIST)/ Stephanie Servetas (NIST)</i>
BREAK 2:45 PM – 3:00 PM	
3:00 PM – 4:00 PM	NIST RMTM Consortium WG2 - Methods: Tools to Support Next Generation Sequencing as a Rapid Sterility Method, <i>Scott Jackson (NIST) /Tyler Laird (NIST)</i>
4:00 PM – 4:30 PM	Closing Discussion, <i>Scott Jackson (NIST)</i>

Workshop Follow-Up

- Workshop slides and recordings (with permission from speakers)
 - Slides will be posted on the workshop website
 - Recordings will be posted on the shared Consortium drive (members only) and will be available upon request for workshop attendees
- Interested in learning more about the NIST RMTM Consortium?
 - New members are being accepted
 - Contact: rmtm@nist.gov
 - Link to letter of interest form:
 - https://docs.google.com/forms/d/e/1FAIpQLSc9vISdSIxUMu-GJv8iPZm7AXi-sdleEo7_OLEnLXhu-kdU0w/viewform

Acknowledgements

- NIST RMTM Consortium Members
- Standards Coordinating Body
 - Dawn Henke
- NIST Conference Program Office

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