

Welcome to the 2022 NIST Rapid Microbial Testing Methods Workshop

We will be using Slido for live polling
during the workshop.

Please go to Sli.do #RMSTM
on your computer or mobile
device.

Join at
slido.com
#RMSTM



2022 NIST Rapid Microbial Testing Methods Consortium (RMTM) Workshop

Tuesday, April 19, 2022

11:00 AM to 3:30 PM (ET)

Join at
slido.com
#RMTM



Housekeeping

- This meeting is being recorded
- Please join the meeting with your full name and organization
- Please use the chat for comments/questions/feedback

Attendee Polls

Join at
slido.com
#RMTM



How to Join the Consortium

- Submit a letter of interest
- Review and sign the agreement sent by NIST
- Connect to the shared drive, join working groups, contribute!

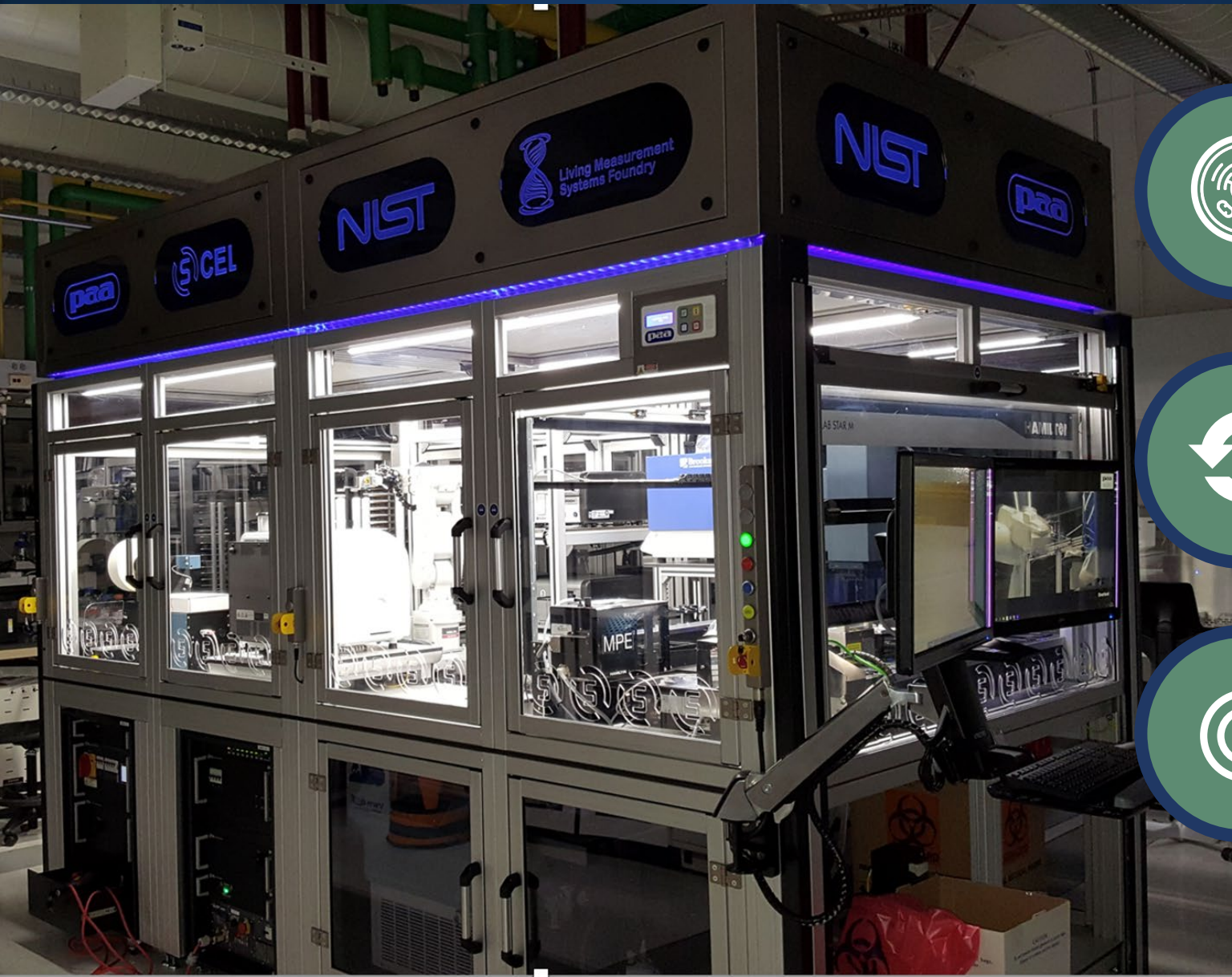


NIST and Rapid Microbial Testing Methods (RMTM) Consortium Overview

Sheng Lin-Gibson

April 19, 2022

Building the Next Generation Biometrology and Engineering Biology Capabilities to support U.S. Biotechnology Enterprise and Bioeconomy



Advanced Biometrology

Unprecedented measurement capabilities to quantify complex *living* systems and processes



Design-Build-Test-Learn

Tools, platforms, and data/knowledge to predictively engineer biological systems to accelerate innovation in R&D and to advance biomanufacturing



Standards

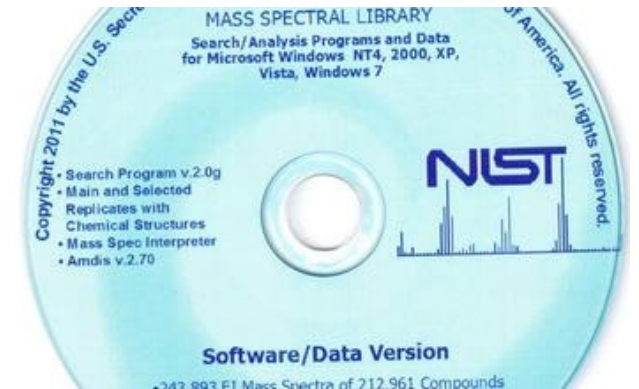
Standards and related infrastructure to accelerate technology development and translation/clinical use

NIST measurement services



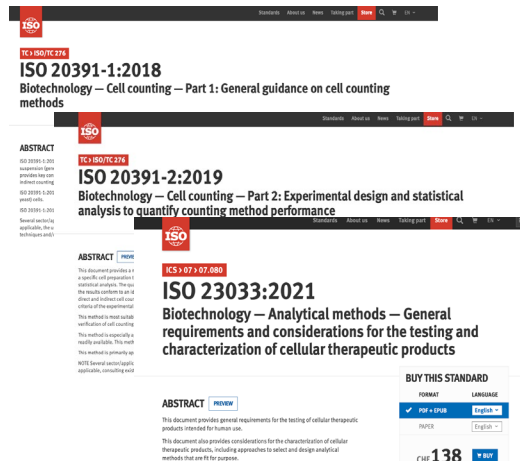
Reference
Materials

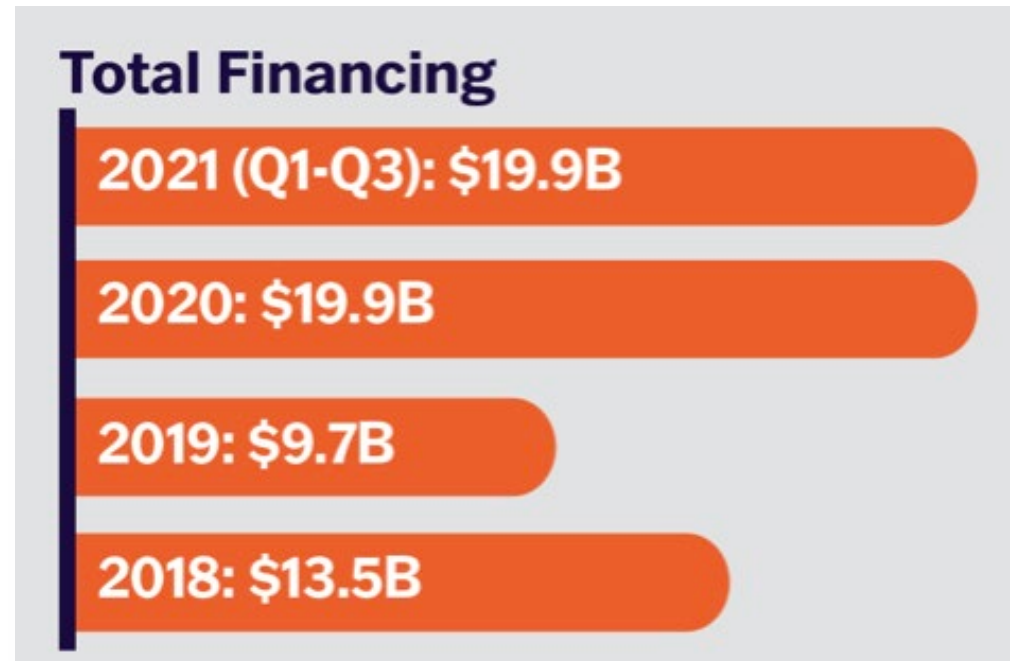
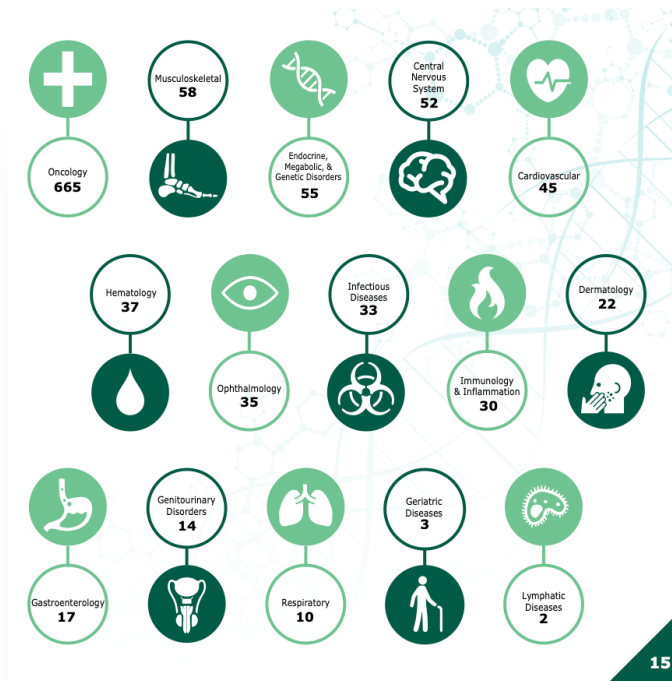
Reference
Data



Documentary
Standards

Calibration
Services





– Alliance for Regenerative Medicine; Q3 2021

NIST has been working with FDA and SCB to develop standards to support a growing **regenerative medicine** and **advanced therapy** industry

NIST Consortia: Public-Private Partnership to address pre-competitive challenges



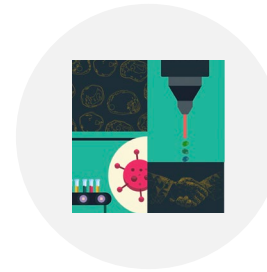
NIST GENOME IN A BOTTLE (GIAB) CONSORTIUM

Provides authoritative characterization of benchmark human genomes



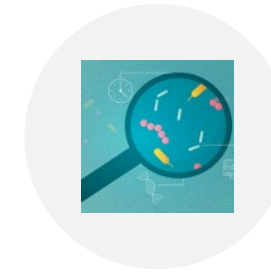
NIST GENOME EDITING CONSORTIUM

Develops measurement solutions and standards needed to increase confidence and reduce risks



NIST FLOW CYTOMETRY STANDARDS CONSORTIUM

Accelerates the adoption of quantitative flow cytometry in biomanufacturing



NIST RAPID MICROBIAL TESTING METHODS CONSORTIUM

Addresses measurements and standards needed to increase confidence in the use of rapid testing

<https://www.nist.gov/mml/bbd>

Advanced Therapy Products Need Modern Microbial Methods

Cell therapies (*Living drugs*)

- Decreased manufacturing time
- Short shelf-life
- Critically needed for seriously ill patients

Manufacturing of advanced therapies, vaccines, and other biopharmaceutical products

Product sterility testing

USP <71> Based on culturing in broth for 14-21 days

21 days for sterility testing is too long!



ARTICLES

<https://doi.org/10.1038/s41551-021-00842-6>

nature
biomedical engineering



Rapid manufacturing of non-activated potent CAR T cells

Saba Ghassemi^{1,2}✉, Joseph S. Durgin¹, Selma ...
Marilia Pinzone², Feng Shen¹, ...
Shantanu Reddy², ...
... O'Doherty², Roddy S. O'Connor^{1,2} and

Cells generated within 24 h (vs 2 weeks)

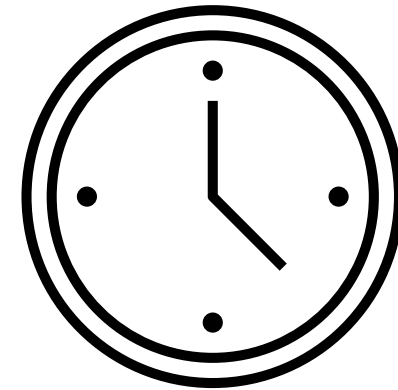
NATURE BIOMEDICAL ENGINEERING | VOL 6 | FEBRUARY 2022 | 118-128 | www.nature.com/natbiomedeng

Rapid Microbial Testing Methods (RMTM)

Example Rapid Methods

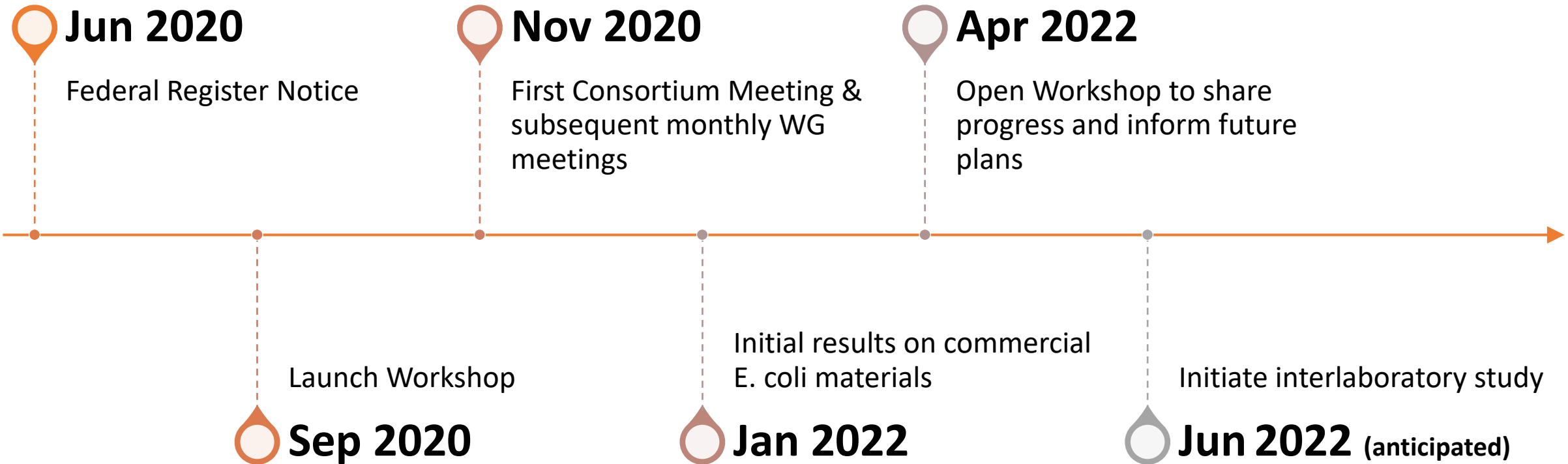
- Respiration (CO₂ detection)
- ATP
- Solid phase cytometry
- PCR
- Raman/IR spectroscopy
- Flow cytometry
- Mass spectrometry

Results in <24 h up to 2-7 days



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

RMTM Consortium Timeline



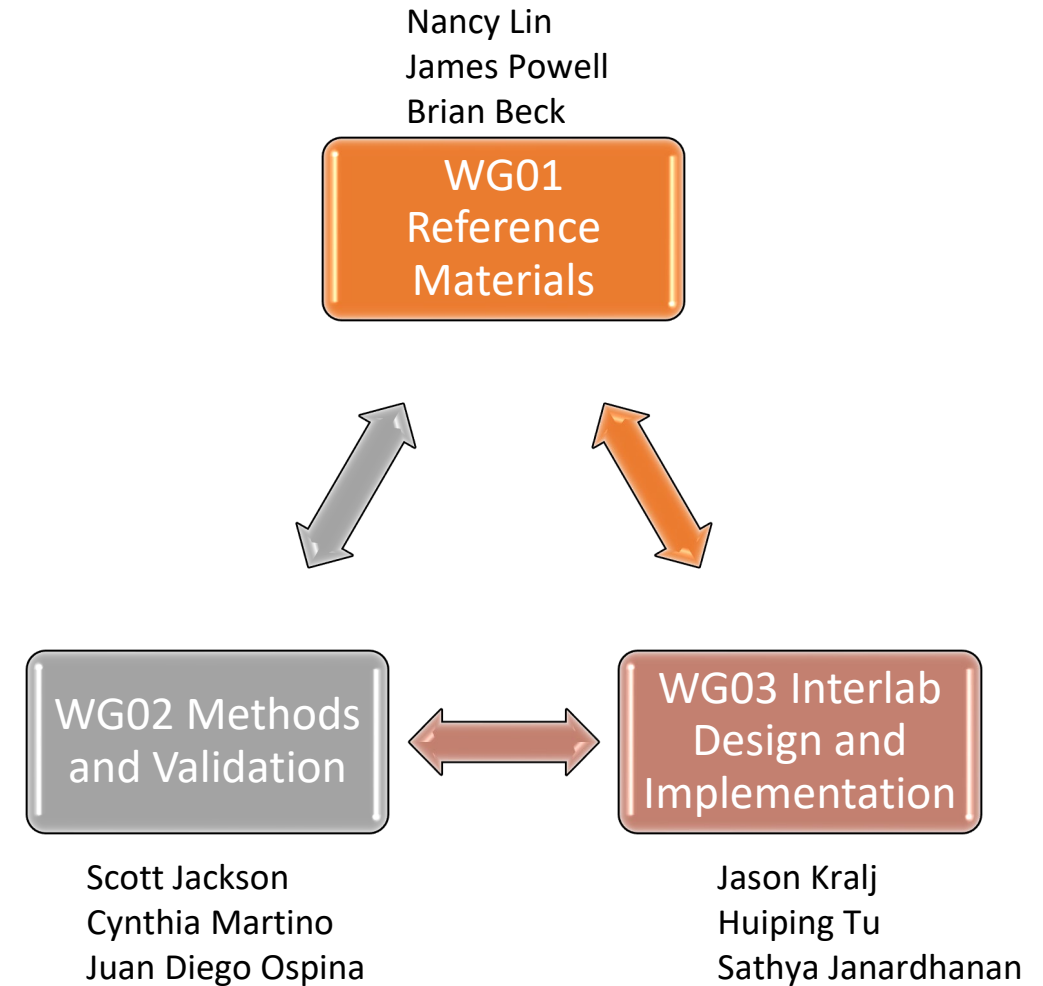
Consortium Organization

NIST Team

- **Scott Jackson**
- **Nancy Lin**
- Tara Eskandari
- Sheng Lin-Gibson
- Jason Kralj
- Stephanie Servetas
- Kirsten Parratt
- Sandra Da Silva
- Joy Dunkers
- Monique Hunter
- Jennifer Dootz
- Shaswat Koirala

Standards Coordinating Body

- Dawn Henke
- Melody Sanders
- Katie Zander



30 Consortium Members (CRADA, no fee)

- Agilent Technologies
- Allele Biotechnology and Pharmaceuticals, Inc.
- AlloSource
- American Type Culture Collection (ATCC)
- Apsis Healthcare Systems, LLC
- bioMérieux
- Bionique Testing Laboratories, Inc.
- Bristol Myers Squibb
- Defense Biological Product Assurance Office, CBRND-EB, JPEO, DoD
- EMD Millipore Corporation (MERCK Kommanditgesellschaft auf Aktien)
- EzBiome Inc
- Gentech Biosciences
- George Washington University - Computational Biology Institute
- Independent (Spencer Hoover)
- Independent (Vicki Barbur)
- Latham BioPharm Group
- Microbiological Consulting, LLC
- Microbiologics, Inc.
- Microbiology Consultants, LLC
- NIH Clinical Center - Center for Cellular Engineering
- National Institute for Biological Standards and Control (NIBSC)
- National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)
- Sartorius Aktiengesellschaft
- Siolta Therapeutics
- SmartGene GmbH
- United States Pharmacopeial Convention
- University of Delaware (Udel)
- U.S. Food and Drug Administration
- Vericel Corporation
- Weill Medical College of Cornell University

5 Advanced Therapy Producers

10 Assay/RM Manufacturers

6 Consultants/CROs

4 Government

3 Academia

2 Non-profit/Other