



Orientation to Antimicrobial Subcommittees

January 2023



Introduction

What to Expect





Overview

- We will describe:
 - More about CLSI.
 - How to navigate the upcoming meetings.
 - Organizational details—including meeting dates, document development, and how to get involved with our three subcommittees:
 - Antimicrobial susceptibility testing (AST SC)
 - Antifungal (AFST SC)
 - Veterinary Antimicrobial Susceptibility Testing (VAST SC)





Antibacterial Testing

- Anaerobes
- Fastidious and Uncommon Bacteria

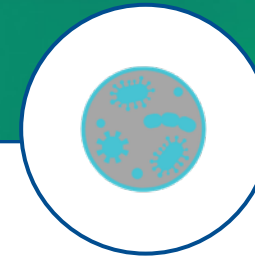


Antifungal Testing

- Yeasts
- Moulds



Veterinary Antibacterial Testing



Mycobacteria, *Nocardia* spp., Other Actinomycetes

CLSI Committees and Documents Related to Antimicrobial Susceptibility Testing



Your First CLSI Meeting

- Unless otherwise noted, you will be considered a “**guest.**”
- You may also become a “**volunteer**” and have the option to find a fit with one or more working groups (WG) or subcommittees (SC).
- The processes and timelines for the CLSI subcommittees may vary and will be discussed today.





Follow Along

Use the meeting materials to follow along with each presentation.



Network and Ask Questions

Talk to others on breaks and during meals and ask questions during sessions.



Try Not to Multitask

We get it, we're all busy. But you'll get more out of the meeting if you're fully focused.



Attend the New Attendee Meet-and-Greet

Meet other new attendees, staff, and liaisons from the Outreach Working Group who are excited to meet you.

Making the Most of Your First Meeting



About CLSI

An Overview



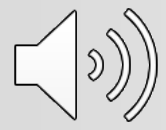


Who is CLSI?

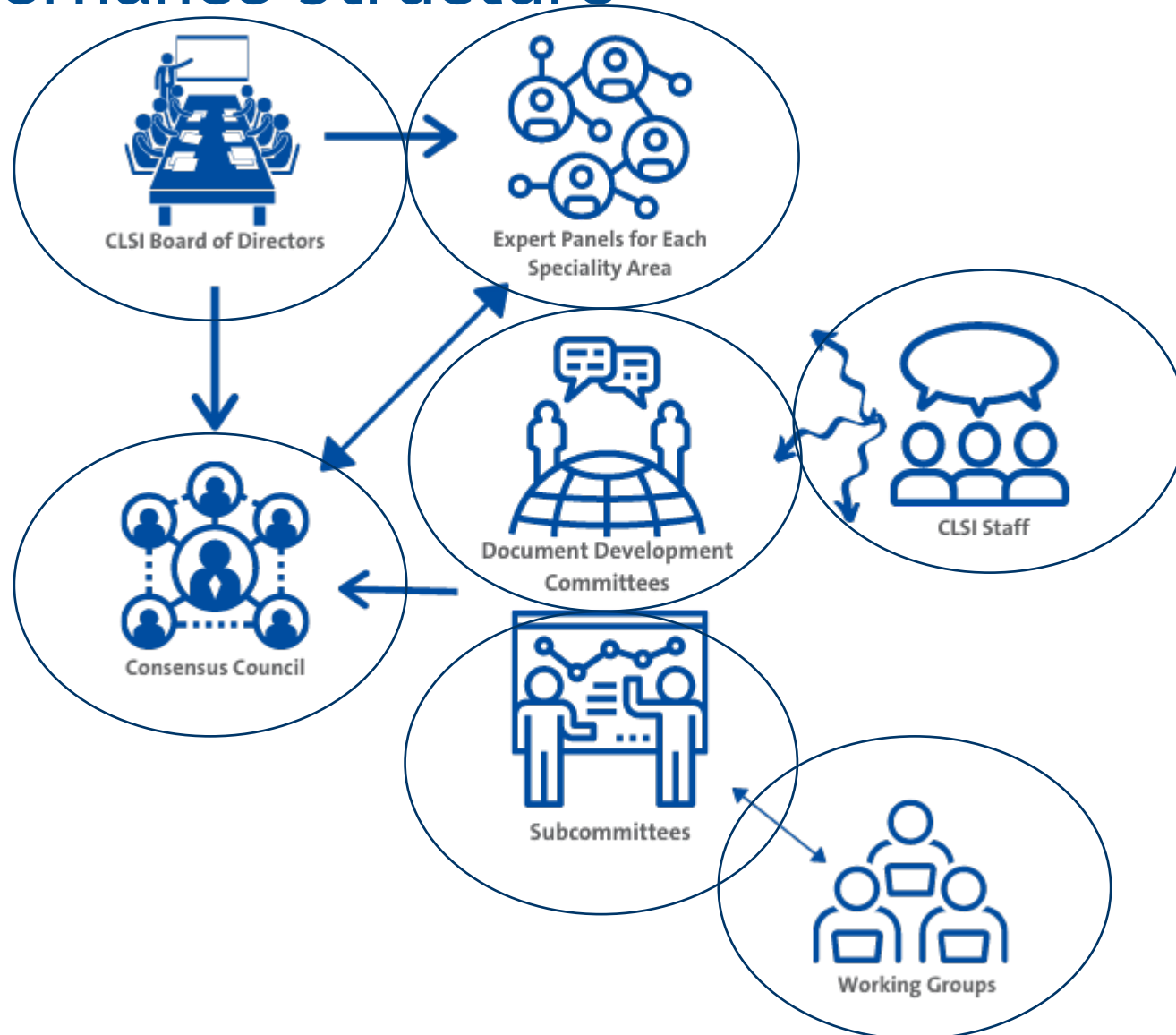
Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit **standards development** organization that brings together the global laboratory community for a common cause: fostering excellence in laboratory medicine.

CLSI documents cover most areas of the medical laboratory; today we will just focus on microbiology.

Being a member of CLSI—through your organization’s membership or as an individual member—allows you to participate in the volunteering process.

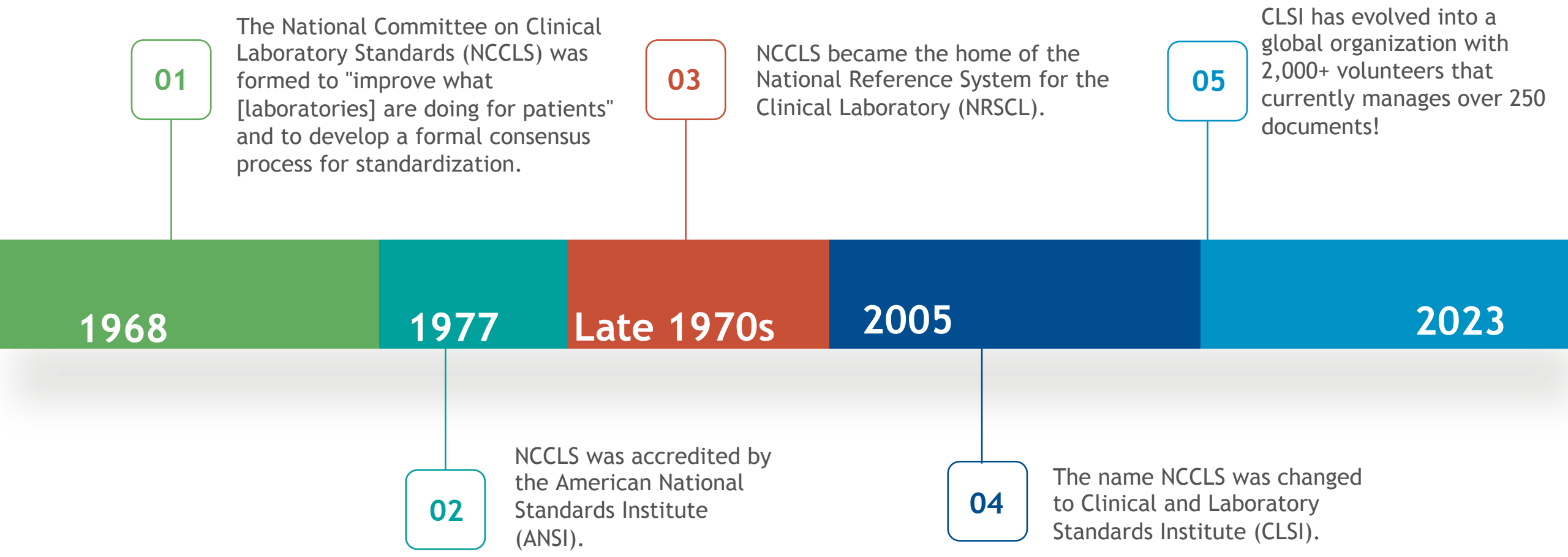


CLSI Governance Structure





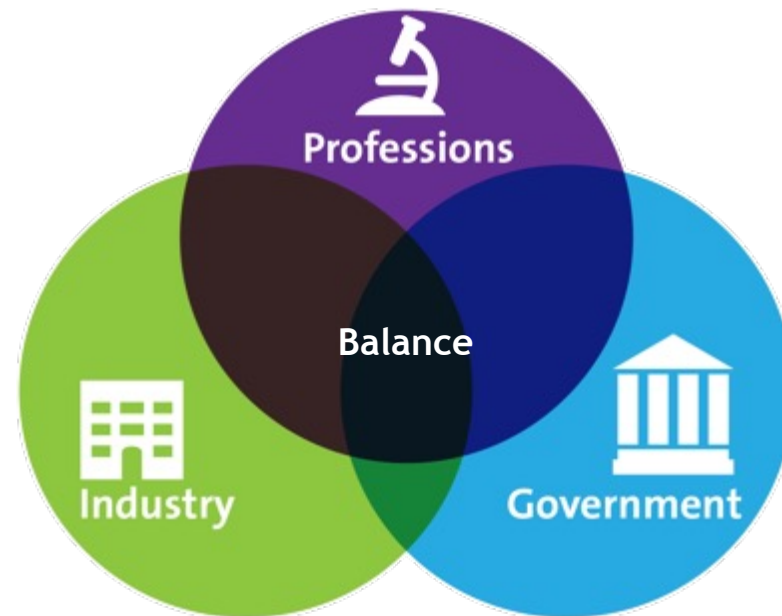
History of CLSI





CLSI Process

- Documents are vetted through the consensus process.
- Meeting minutes and select additional materials are available to the public on the [CLSI website](#).
- Comments from meeting attendees and from users of documents are actively encouraged and addressed.
- Final products = standards and guidelines documents and other materials/programs to support the standards.



Meetings are open to everyone!



Consensus Standards and Guidelines

- Some CLSI documents are **guidelines**, while others qualify as **standards**.
- **Standard** = Identifies essential requirements for materials, methods, or practices for voluntary use in an unmodified form. Examples include M02 and M07.
- **Guideline** = Identifies requirements for materials, methods, or practices for voluntary but recommended use. Examples include M23 and M45.



CLSI Volunteers

Diverse representation (worldwide) from all three constituencies. Interests between constituencies are balanced.

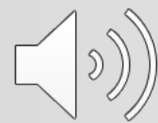
Industry	Government	Professions
IVD Manufacturers	Public Health Agencies	Clinical Laboratories
Pharmaceutical Manufacturers	Regulatory Bodies	Research Laboratories
LIS/HIS Vendors	Accrediting Organizations	Health Care Delivery Systems
Suppliers		Educational Institutions
Clinical Research Organizations		Professional Societies, Trade Organizations
		Standards Organizations

Abbreviations: IVD, *in vitro* diagnostic; LIS, laboratory information system; HIS (hospital information system).



About the AST Subcommittee





AST Subcommittee Mission

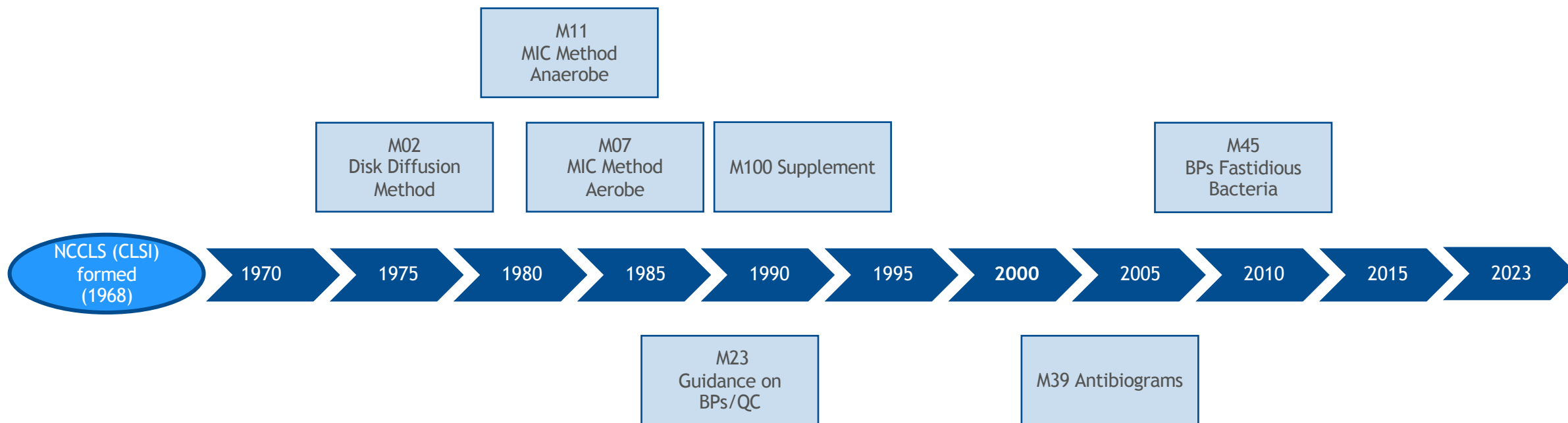
The mission of the AST SC is to:

- Develop standard reference methods for antimicrobial susceptibility tests.
- Provide quality control parameters for standard test methods.
- Establish breakpoints for the results of standard antimicrobial susceptibility tests and provide epidemiological cutoff values when breakpoints are not available.
- Provide suggestions for testing and reporting strategies that are clinically relevant and cost effective.
- Continually refine standards and optimize detection of emerging resistance mechanisms through development of new or revised methods, breakpoints, and quality control parameters.
- Educate users through multimedia communication of standards and guidelines.
- Foster a dialogue with users of these methods and those who apply them.

The mission statement is listed in the front of each AST document!



Introduction of Timeline of First Publication of Major CLSI AST SC Documents



Abbreviations: BPs, breakpoints; QC, quality control.



Volunteer Responsibilities: Subcommittees

- **Chairholder - James Lewis, II, PharmD, FIDSA**
 - Ensures that committee objectives are met.
 - Appoints Members and Advisors.
 - Plans, monitors, and schedules the document revision process.
 - Moderates the discussions at face-to-face or virtual meetings.
 - Does not vote (except in select situations).
- **Vice-Chairholder - Amy J. Mathers, MD, D(ABMM)**
 - Serves as leader in Chairholder's absence.
 - Learns process in preparation for role as Chairholder and when rotating from the role of Chairholder, assists the new Chairholder in the transition.
 - Does not vote.



Volunteer Responsibilities: Subcommittees

- **Members - Appointed**
 - Must include representatives from each of the three constituencies
 - Serve as authors and subject matter experts
 - Serve on working groups (WGs)
 - Vote on technical decisions and draft documents
- **Advisors - Appointed**
 - Provide technical expertise to the SC
 - Serve on WGs
 - Provide input on draft documents submitted for approval

Appointed members and advisors serve one-year terms that are renewable yearly for up to four years.



Volunteer Responsibilities: Subcommittees

- **Reviewers**

- May serve on WGs and/or provide technical input
- Review and comment on draft documents
- Anyone with an interest in the AST SC's goals can become a reviewer, make suggestions, submit data and join WGs. Identify a WG you would like to join first, then discuss your interests with that WG chair(s). Follow up by simply submitting a request to CLSI by e-mailing standard@clsi.org or filling out a Working Group application on clsi.org/vol.

To become a “volunteer” member, advisor, or reviewer and be added to the official roster, you must submit a disclosure of interests and CV. In addition, an administrative fee is required which is usually covered through one’s organizational CLSI membership.

- ***Guests***

- *Have not submitted a request to become a “volunteer”*
- *Are not on the official roster*
- *Can provide input but cannot become a WG member until added to the SC as a Reviewer*



CLSI Subcommittee Volunteer Opportunities

Function	Member	Advisor	Reviewer	Guest
Appointed by SC chair	X	X	X	
Serve on WG	X	X	X	
Contribute - raise issues	X	X	X	X
Contribute - technical expertise	X	X	X	
Contribute - provide data	X	X	X	X
Review/comment on draft documents	X	X	X	X
Vote (In WG meeting)*	X	X	X	
Vote (At plenary session)	X			

* If officially appointed as a WG member



Documents Managed by CLSI AST Subcommittee

No.	Document	Revision Cycle
M02*	Disk diffusion method (aerobes)	3-5 years
M07*	MIC testing methods (aerobes)	3-5 years
M11*	MIC testing methods (anaerobes)	3-5 years
M100*	Tables (disk and MIC for aerobes and MIC for anaerobes)	Annual
M23†	Guidance for setting breakpoints, setting QC ranges, making recommendations in AST documents	5 years (or as needed)
M39†	Antibiograms	5 years (or as needed)
M45†	Fastidious organism tables	5 years (or as needed)

* Standards
† Guidelines



“Standing” Working Groups of AST Subcommittee

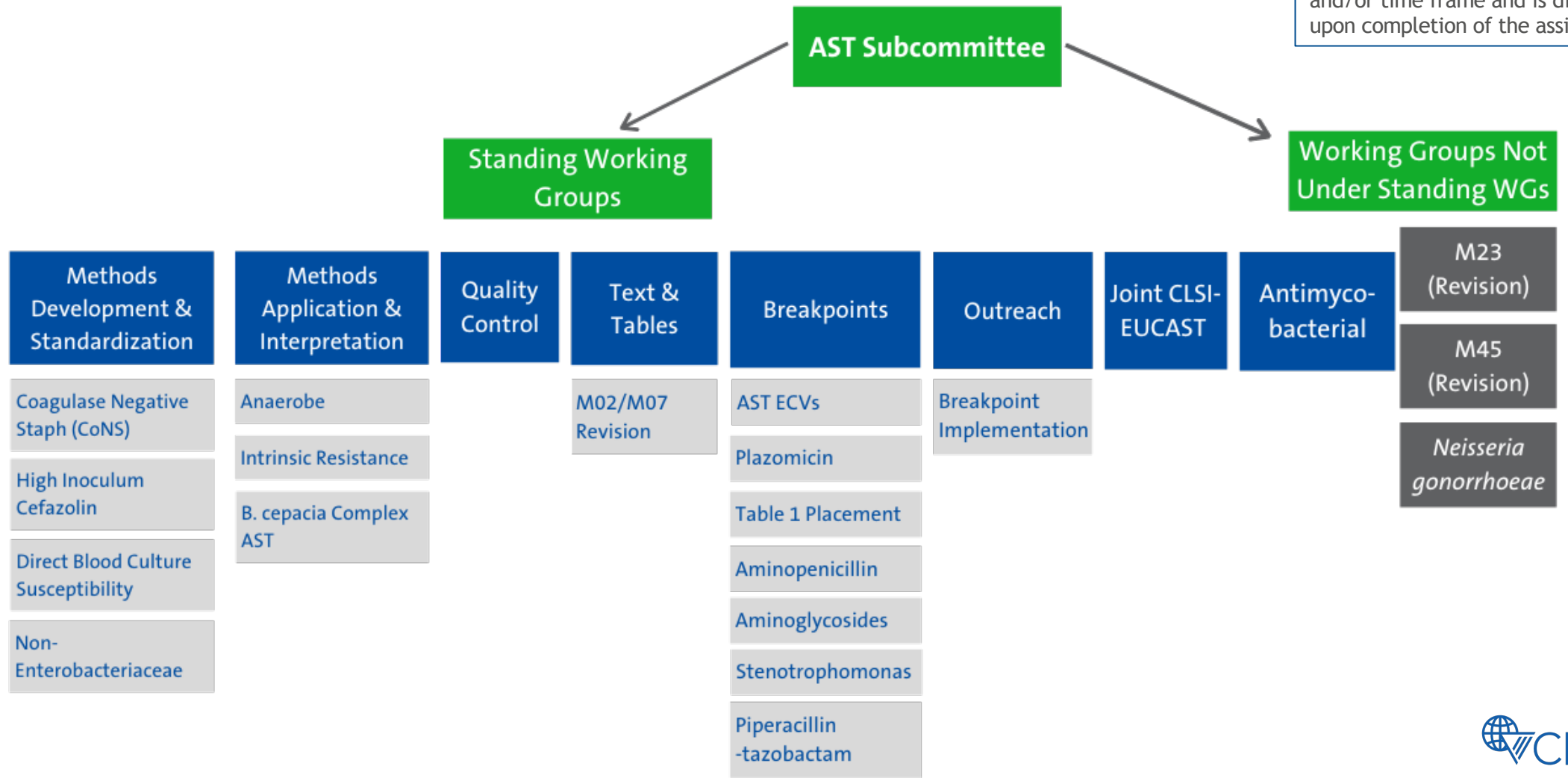
Working Group	Primary Function
Joint CLSI-EUCAST	Strives to harmonize CLSI and EUCAST recommendations (eg, disk content selection)
Methods Development and Standardization	Develops or modifies test methods
Methods Application and Interpretation	Determines how a test method can be used
Quality Control	Sets QC ranges
Text and Tables	Incorporates approved recommendations from other WGs into M100
Breakpoint	Sets clinical breakpoints and epidemiological cutoff values (ECVs)
Outreach	Provides educational and informational outreach to stakeholders
Antimycobacterial	Reviews and approves new QC ranges and BPs for <i>Mycobacteria</i> spp.

All WGs review data and make recommendations consistent with their primary function.



AST SC Standing WGs and Ad hoc WGs: 2023

An *Ad hoc WG* (noted in light grey boxes below) is under one of the eight *Standing WGs*. *Ad hoc WG* usually has an assignment that is limited in scope and/or time frame and is disbanded upon completion of the assignment.





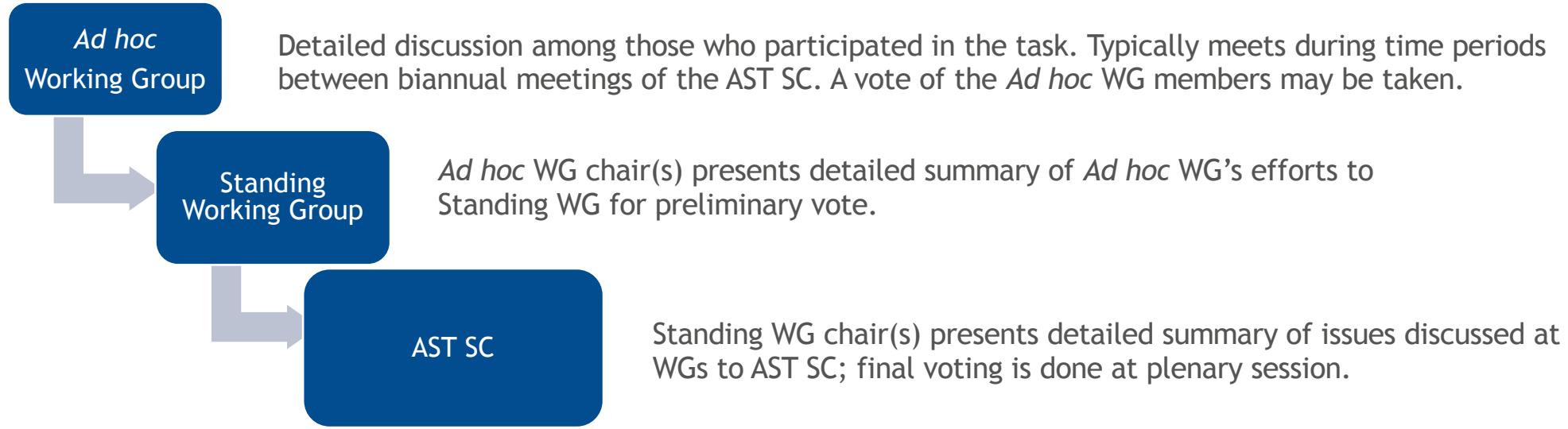
Attending AST SC *Ad hoc* WG, Standing WG and Plenary Sessions*

Meeting Type	Status
<i>Ad hoc</i> WG	Open to <i>Ad hoc</i> WG members of the respective <i>Ad hoc</i> WGs; contact <i>Ad hoc</i> WG chair if you wish to contribute to the <i>Ad hoc</i> WG.
Other WGs not under “Standing WG” [eg, M39 (antibiograms), <i>Neisseria gonorrhoeae</i>]	Open to WG members of the respective WGs; contact WG chair if you wish to contribute to the WG.
Standing WG	Open to all registrants
Plenary Session	Open to all registrants

* If you are not an appointed member of the AST SC or WG.

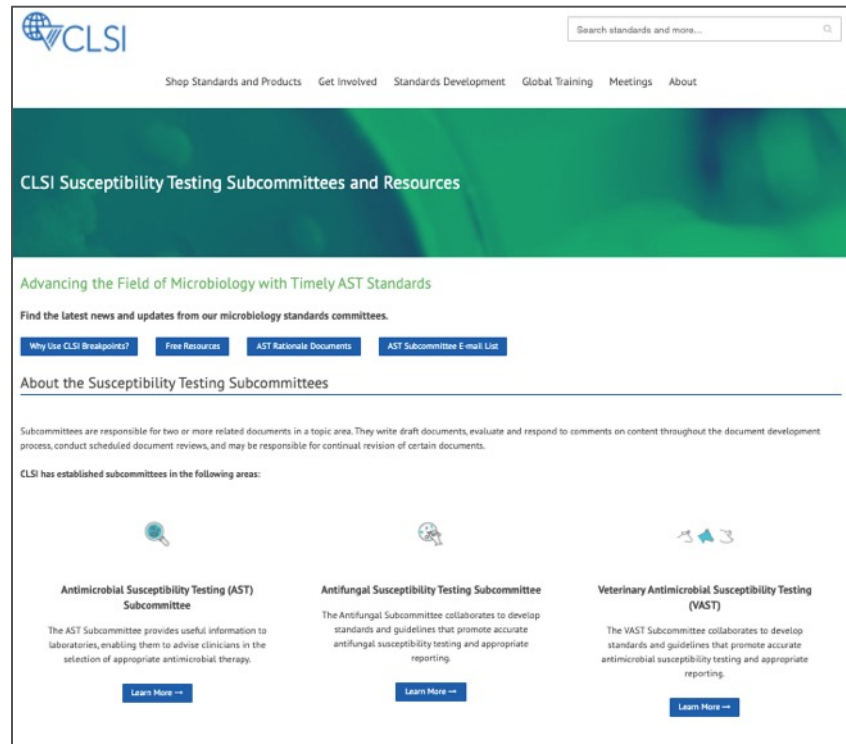


Taking an Issue to Approval!





How can you learn more about CLSI AST SC and ongoing AST SC projects?



clsi.org/micro

Visit the link above to find:

- Minutes/Materials from previous meetings.
- Current and past AST SC News Updates.
- PowerPoints from Workshop presentations.
- Dates of upcoming meetings.
- ...and much more!



About the Subcommittee on Antifungal Susceptibility Tests





Subcommittee (SC) on Antifungal Susceptibility Tests

The SC on Antifungal Susceptibility Tests is responsible for:

- Reviewing data and setting antifungal agent ECVs and breakpoints for yeasts and filamentous fungi.
- Reviewing data and setting QC ranges for new antifungal agents.
- Managing antifungal susceptibility testing documents.

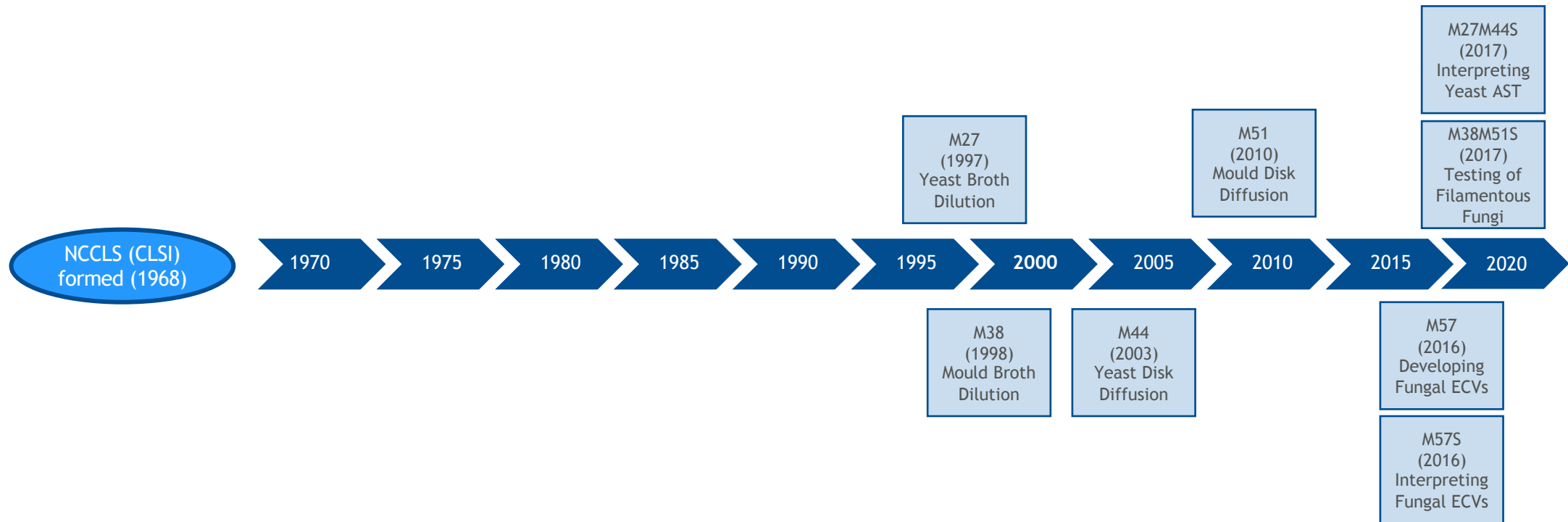


Volunteer Leadership: SC on Antifungal Susceptibility Tests

- **Chairholder** - Philippe J. Dufresne, PhD, RMCCM
- **Vice-Chairholder** - Gary W. Procop, MD, MS



Timeline of CLSI SC on Antifungal Susceptibility Tests Documents





Documents Managed by CLSI SC on Antifungal Susceptibility Tests

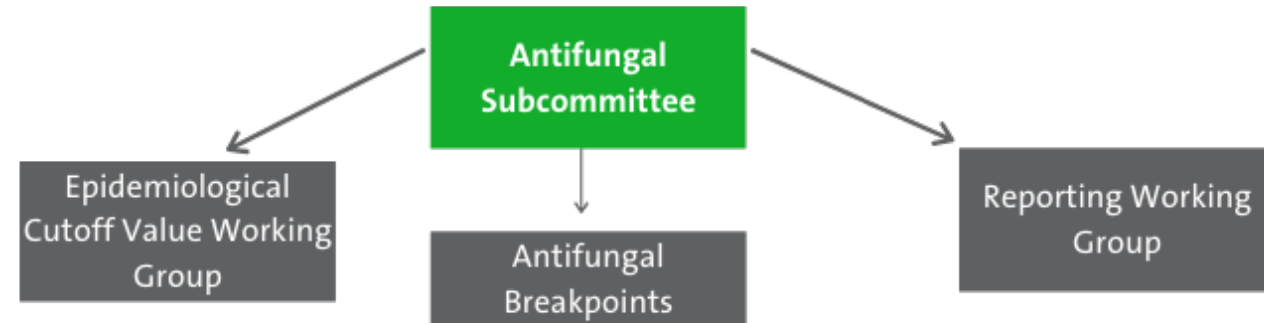
No.	Document	Revision Cycle
M27*	MIC testing methods (yeasts)	3-5 years
M38*	MIC testing methods (filamentous fungi)	3-5 years
M44†	Disk diffusion testing methods (yeasts)	3-5 years
M51†	Disk diffusion testing methods (filamentous fungi)	Archived Fall 2021
M57†	ECV development guideline (yeasts and filamentous fungi)	3-5 years
M57S (Formerly M59)*	ECVs for antifungal susceptibility testing	As needed
M27M44S (Formerly M60)*	Performance standards for antifungal susceptibility testing of yeasts	As needed
M38M51S (Formerly M61)*	Performance standards for antifungal susceptibility testing of filamentous fungi	As needed

* Standards
† Guidelines



Working Groups of SC on Antifungal Susceptibility Tests

Working Group	Primary Function
Epidemiological Cutoff Value	Reviews ECV data and recommends ECVs for yeasts and filamentous fungi
Antifungal Breakpoints	Setting antifungal clinical BPs to present to the full Antifungal SC for approval and providing input to the sponsor on any missing data
Reporting	Develop guidelines for reporting of antifungal agents from specific body sites and guidance for labs of intrinsic resistance of yeasts and filamentous fungi to certain antifungal agents





About the VAST Subcommittee





VAST Subcommittee Mission and Responsibilities

Develop and promote performance standards, breakpoints, and interpretive categories for *in vitro* antimicrobial susceptibility testing of bacteria isolated from animals. This SC is responsible for:

- Developing standard reference methods for antimicrobial susceptibility tests.
- Providing quality control parameters for standard test methods.
- Establishing breakpoints and interpretive categories for the results of standard antimicrobial susceptibility tests performed on veterinary pathogens.
- Providing suggestions for testing and reporting strategies that are clinically relevant and cost effective.
- Continually refining standards through development of new or revised methods, breakpoints, interpretive categories, and quality control parameters.
- Educating users through multimedia communication of standards and guidelines.
- Fostering a dialogue with users of these methods and those who apply them.

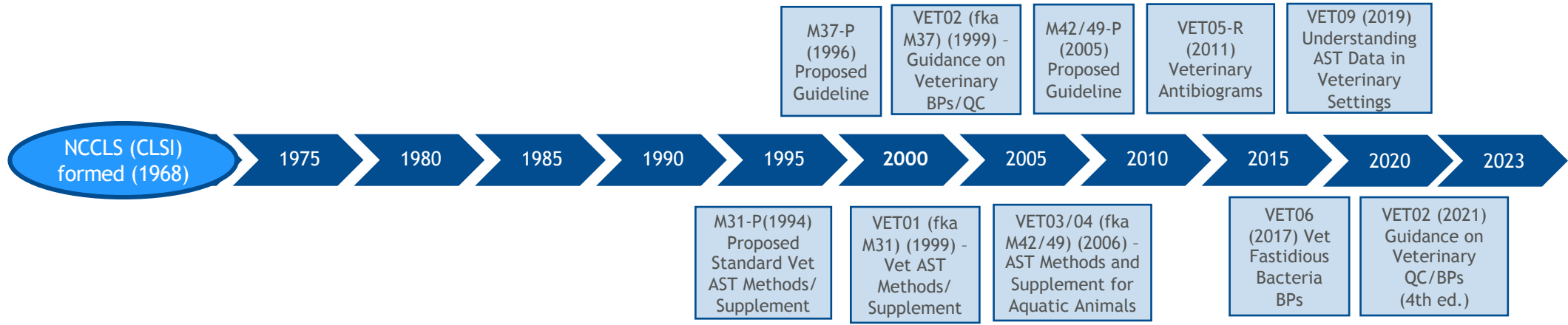


Volunteer Leadership: VAST Subcommittee

- **Chairholder** - Dubraska V. Diaz-Campos, DVM, PhD
- **Vice-Chairholder** - Brian V. Lubbers, DVM, PhD



Timeline of CLSI VAST SC Documents



Abbreviations: BPs, breakpoints; QC, quality control; fka, formerly known as.



Documents Managed by CLSI VAST Subcommittee

Working Group	Primary Function
Editorial/VAST Breakpoint Tables (VET01 Editorial WG)	Provides updates to VET01S, the informational supplement for the CLSI standard VET01
Working Group on Aquatic Animals	Reviews and makes recommendations on the breakpoint tables in the VET04S
Generic Drugs (GWG)	Develops or revises breakpoints (BPs) and interpretive categories (ICs) for older compounds and generic drugs, for which there is no longer a sponsor (pharmaceutical company) or need to be updated based on new information or data.
Understanding AST Data in Veterinary Settings	Revises VET09 concurrently with revisions of the VET01S to include new breakpoints and information published in the VET01S.
Bovine Mastitis Interpretive Criteria	Provides guidance on clinical breakpoint determinations for compounds with mastitis approvals but no mastitis-specific breakpoints.
PD Cutoff Values for Establishing Breakpoints	Reviews pharmacokinetics (PK)/ pharmacodynamics (PD) information. Develops, reviews, and updates VET02 tables and recommends PK/PD index values for each antimicrobial class.
Veterinary Breakpoint Rationale	Drafts rationale documents for approved sponsored and generic drug veterinary-specific breakpoints
Education	Identifies outreach and educational opportunities in the veterinary diagnostic community for users and potential users of VAST-supported CLSI documents, and to promote good antimicrobial stewardship.
Ad Hoc Working Group (AHWG) on Molecular Antimicrobial Susceptibility Testing (AST)	Develop recommendations for molecular AST method application for veterinary research and diagnostic work.

- * Standards
- † Guidelines
- ‡ Reports

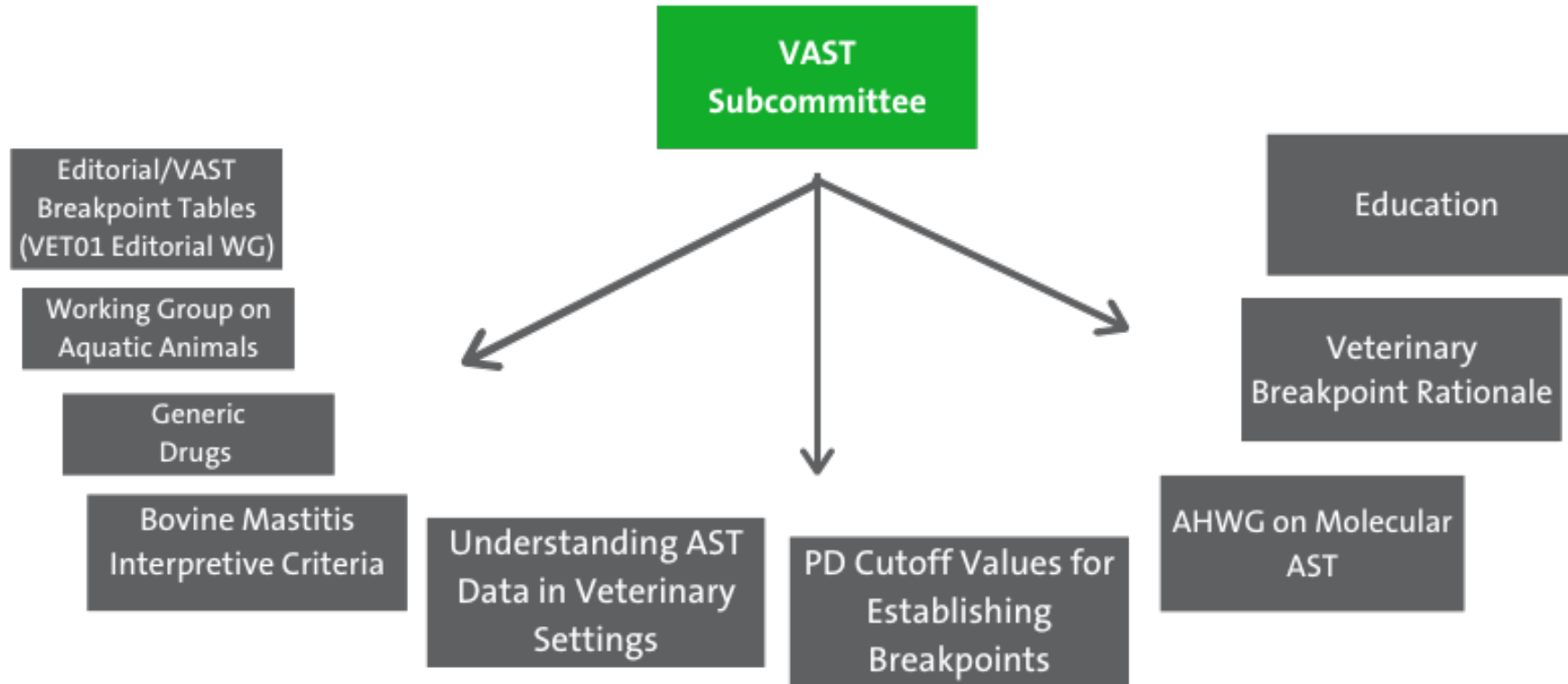


“Standing” Working Groups of VAST Subcommittee

Working Group	Primary Function
Editorial/VAST Breakpoint Tables (VET01 Editorial WG)	Provides updates to VET01S, the informational supplement for the CLSI standard VET01
Working Group on Aquatic Animals	Reviews and makes recommendations on the breakpoint tables in the VET04S
Generic Drugs (GWG)	Develops or revises breakpoints (BPs) and interpretive categories (ICs) for older compounds and generic drugs, for which there is no longer a sponsor (pharmaceutical company) or need to be updated based on new information or data
Understanding AST Data in Veterinary Settings	Revises VET09 concurrently with revisions of the VET01S to include new breakpoints and information published in the VET01S
Bovine Mastitis Interpretive Criteria	Provides guidance on clinical breakpoint determinations for compounds with mastitis approvals but no mastitis-specific breakpoints
PD Cutoff Values for Establishing Breakpoints	Reviews pharmacokinetics (PK)/ pharmacodynamics (PD) information. Develops, reviews, and updates VET02 tables and recommends PK/PD index values for each antimicrobial class
Veterinary Fastidious Medium	Evaluates feedback received once veterinary laboratories begin using the new MHF-Y media
Veterinary Breakpoint Rationale	Drafts rationale documents for approved sponsored and generic drug veterinary-specific breakpoints
Education	Identifies outreach and educational opportunities in the veterinary diagnostic community for users and potential users of VAST-supported CLSI documents, and to promote good antimicrobial stewardship



“Standing” Working Groups of VAST Subcommittee





Becoming Involved With Subcommittees





CLSI Subcommittee Meeting Schedule

January-February	Meeting
January-May	Background Studies and More
May	Submit Agenda Materials
June	Meeting
June-December	Background Studies and More
December	Submit Agenda Materials

* Receive agenda materials approximately 4-6 weeks before the meeting.

You must be a Subcommittee or WG member or register for the meeting to receive the agenda materials.

The AST SC meets twice a year. Decisions are made at these meetings and become “final” when a document (eg, M100) is published.

The Antifungal SC meets annually in January and will also meet in June, if needed. Decisions are made at these meetings and become “final” when a document (eg, M60) is published.

The Veterinary AST SC meets once or twice a year. Decisions are made at these meetings and become “final” when a document (eg, VET01S) is published.

Much of the work is done by Standing WGs and *Ad hoc* WGs between the January and June meetings.



How can YOU become a Working Group member?

Determine your interest in a particular WG.
Generally, volunteers begin working with an *Ad hoc* WG but can begin with a Standing WG.



Apply online at clsi.org/vol or speak with the SC Chairholder, *Ad hoc* or Standing WG Chairholder, and/or Outreach WG member about participation in a WG.
Make sure you are a “Reviewer.”



Plan to attend a WG session.
Feel free to make suggestions, provide data, offer to work on projects, etc.





Must YOU be a WG member to attend a WG meeting, raise issues, or contribute data?

- No!
- Anyone can raise issues/contribute data that is “new” or that is currently being discussed for the meeting materials.
 - Meet with WG chair (virtually or by e-mail).
- Material must be in the agenda book to be voted upon or used to reach a decision to vote.
 - Deadline for submission of agenda book material is approximately six weeks before the January or June meetings.



Learn about the latest developments.



Learn about new antimicrobial agents and new resistance mechanisms.



Network with leaders in the field (microbiologists, pharmacists, clinicians, representatives from industry, public health workers, etc.)

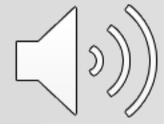


Grow your resumé with your involvement.



Have fun!

Benefits of Becoming a CLSI Volunteer



Ways to Get Involved



To register for the meeting visit clsi.org/meetings.
For questions, contact CLSI Project Managers:
AST & Antifungal | Emily Gomez (egomez@clsi.org)
Antifungal | Chris Lam (clam@clsi.org)
VAST | Lori (Moon) Selden (lseleden@clsi.org)



Review agenda materials that are e-mailed to you prior to the meeting.
Decide which WGs to attend.
(Some issues are ongoing; check previous meeting materials on the CLSI website to review what has been discussed at an earlier meeting.)



Review: M23 (AST), M27M44S (Antifungal), or VET02 (VAST)
These documents describe how breakpoints and QC ranges are established.



Talk with a colleague who has volunteered with CLSI on a Subcommittee or Working Group.



Attend Working Group and plenary sessions.

Steps to ensure YOU will have a rewarding experience at YOUR first CLSI meeting!





Thank you for your interest,
dedication, and commitment!



volunteer@clsi.org

