

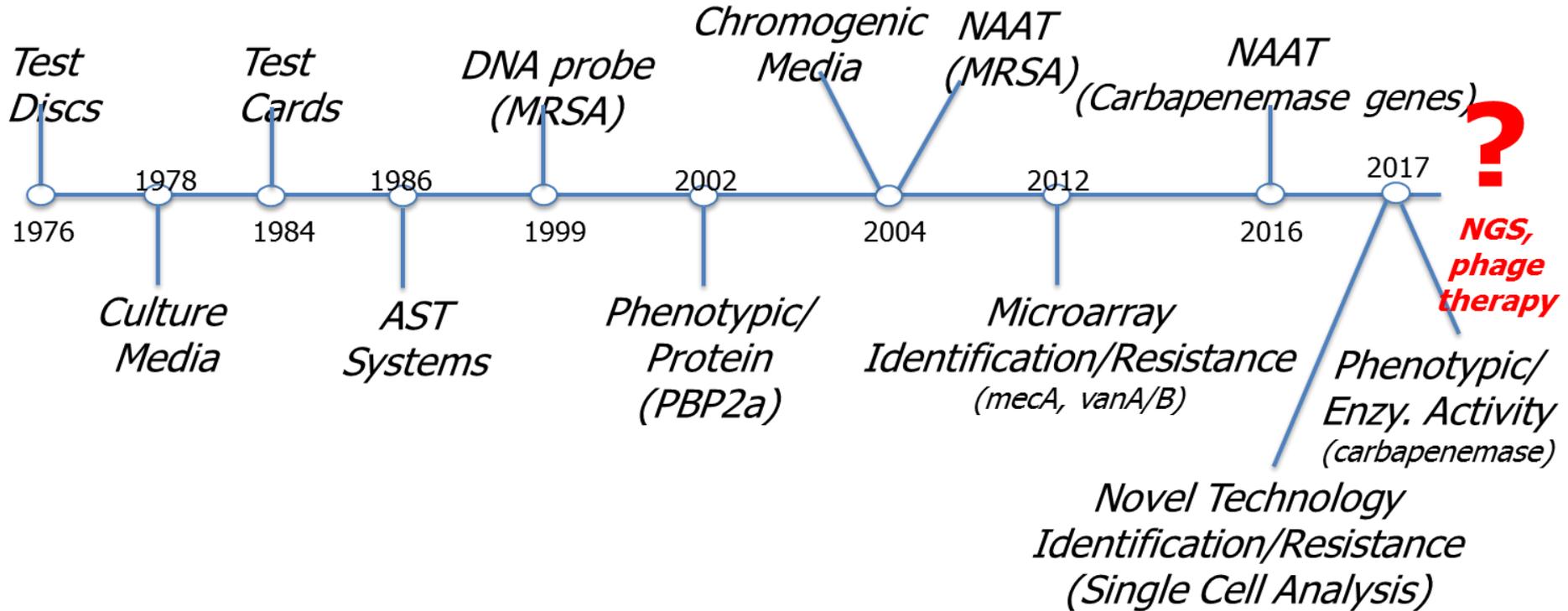
# Diagnostic (AMR) Update

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# Timeline of AMR Tests (FDA)





# Antimicrobial Stewardship (1)

- First biomarker clearance (procalcitonin) to aid clinicians regarding the initiation of antibiotics (outpatient) and discontinuation of antibiotics (inpatient)
  - Follows FDA Panel meeting late last year
  - Very active area of device development and clinical studies
  - Still remains challenging area for clinical validation
- Clearance of Accelerate PhenoTest BC Kit earlier this year
  - First new-technology phenotypic susceptibility devices



# Antimicrobial Stewardship (2)

- Clearance of CRE molecular detection device for infection control and bacterial cultures (2016)
- Ongoing development of multiplex devices that include AMR markers

# Device Development (1)



- Continued support for the FDA-CDC Antimicrobial Resistance Isolate Bank
  - Initiated 2015
  - Likely much more from Dr. Patel 😊
- Continued development of FDA-ARGOS
- September, 2017 workshop on “Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices”
  - Guidance revision and FAQ document under discussion (will be addressed again)
- Presidential Advisory Council on Combating Antibiotic-Resistance Bacteria
- AMR Prize

# Device Development (2)

- Support for new semantic interoperability standard for communicating device coding (LIVD) and for standardized Microbiology coding of laboratory tests (with CDC, NLM, ONC, other partners)
  - Contract with Regenstrief Institute for Microbiology Coding standards
  - Value set workshop anticipated for January, 2018
- New 'breakthrough pathway' for devices

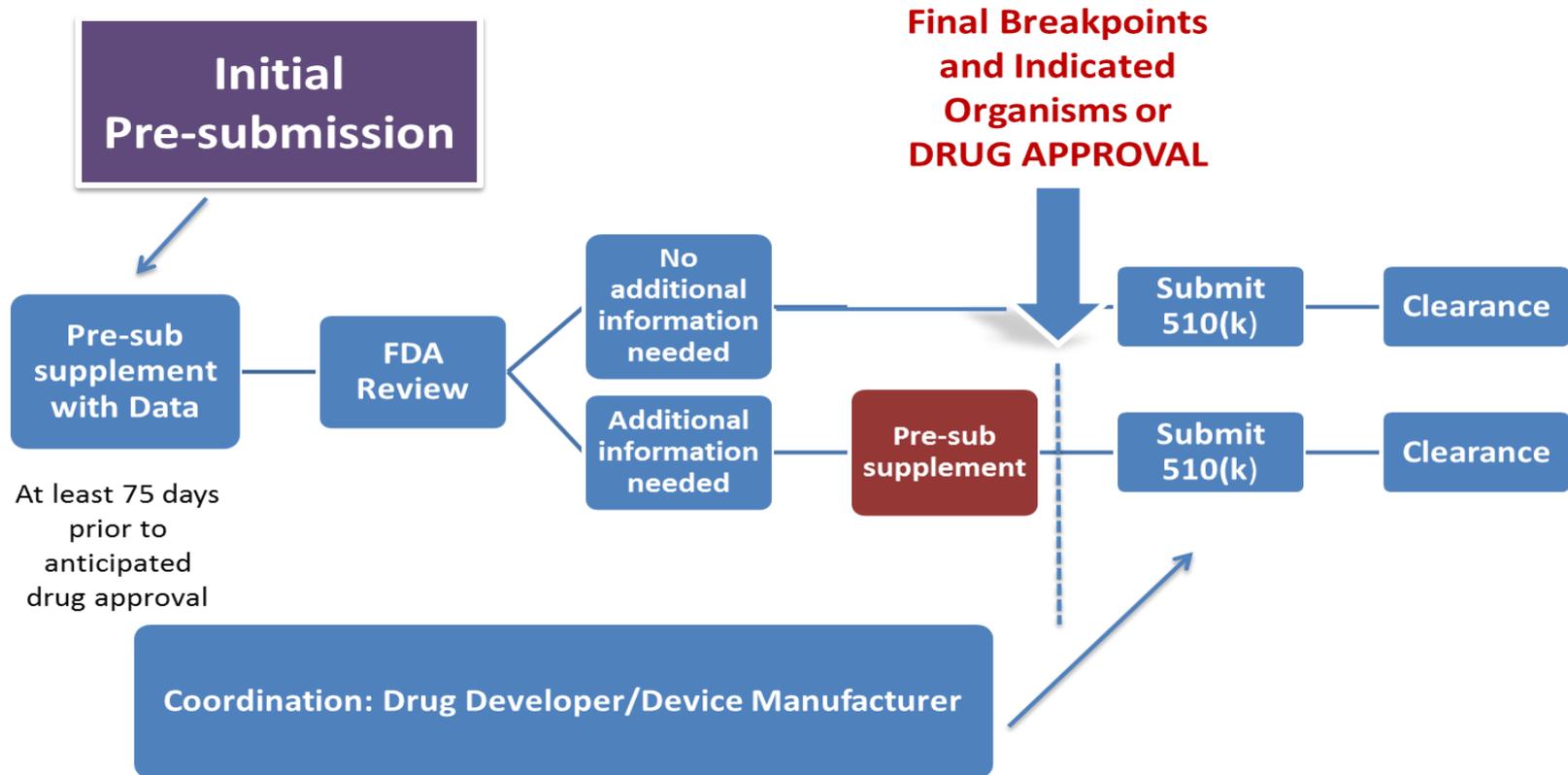
# Prior to 21<sup>st</sup> Century Cures

## Example Timeline from CLSI Susceptibility Criteria Change to AST Device Labeling Change -



CLSI published revised susceptibility criteria for Carbapenem antibiotics in June, 2010 (M100-S20-U). The timeline reflects approximate milestone dates for CDER labeling change submission, CDER approval, CDRH 510(k) device submission, and CDRH 510(k) device clearance. Durations are also approximate.

# Example Coordinated Pathway



# Coordinated Development (2)



- Addresses delays in getting AST devices available near or proximate to drug approvals
- FDA draft guidance published September 2016, final 'shortly'
- Nine pre-submissions
- Recent drug with three AST devices within 44 days of approval
- More recent drug where AST device available before commercial shipping



# Ongoing Issues for AST Device Development

- Fresh specimens for documenting performance: how many and how long...
- 'Lumpers' versus 'splitters': can classes for grouped for AST device development, i.e., each claimed species or Enterobacteriaceae
- Reference method variability for phenotypic AST devices (EA vs. CA)
- Appropriate reference method for genotypic devices

# Ongoing Issues for AST Device Development (2)

- Appropriate comparator methods for polymicrobial specimens
  - Association of resistance markers with identified organisms
- ‘Quantifying’ bacterial load
- How to report information to clinicians
- Incorporating post-marketing information

**Thank you.**

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