Drug and Diagnostic Update

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Antimicrobial Drug Development (1)

- Published/Revised a number of guidance documents for “standard” and unmet need development programs for bacterial diseases
- FDA held a series of public meetings that have informed guidance document development
- Working with EMA and PMDA to converge on recommended trial designs when possible
- GAIN QIDP designations for 71 different antibacterial/antifungal products (136 designations)
- Eight recently approved antibacterial/antifungal drugs had QIDP designation
- Some recent approvals have pursued a more streamlined approach to address unmet medical need

Antimicrobial Drug Development (2)

- Working on implementing the provisions in the 21st Century Cures Act
  - Section 3044. Susceptibility test interpretive criteria for microorganisms; antimicrobial susceptibility testing devices
  - Section 3042. Limited Population Pathway for antibacterial and antifungal drugs (LPAD)
- Working with CDRH colleagues on coordinated development of antimicrobial drugs and diagnostic tests

Device Development (1)

- First clearance for biomarker test to aid clinicians regarding initiation of antibiotics (outpatient) and discontinuation of antibiotics (inpatient)
- Clearance of new-technology device with for rapid phenotypic susceptibilities
- Continued support for the FDA-CDC Antimicrobial Resistance Isolate Bank
- Continued development of FDA-ARGOS

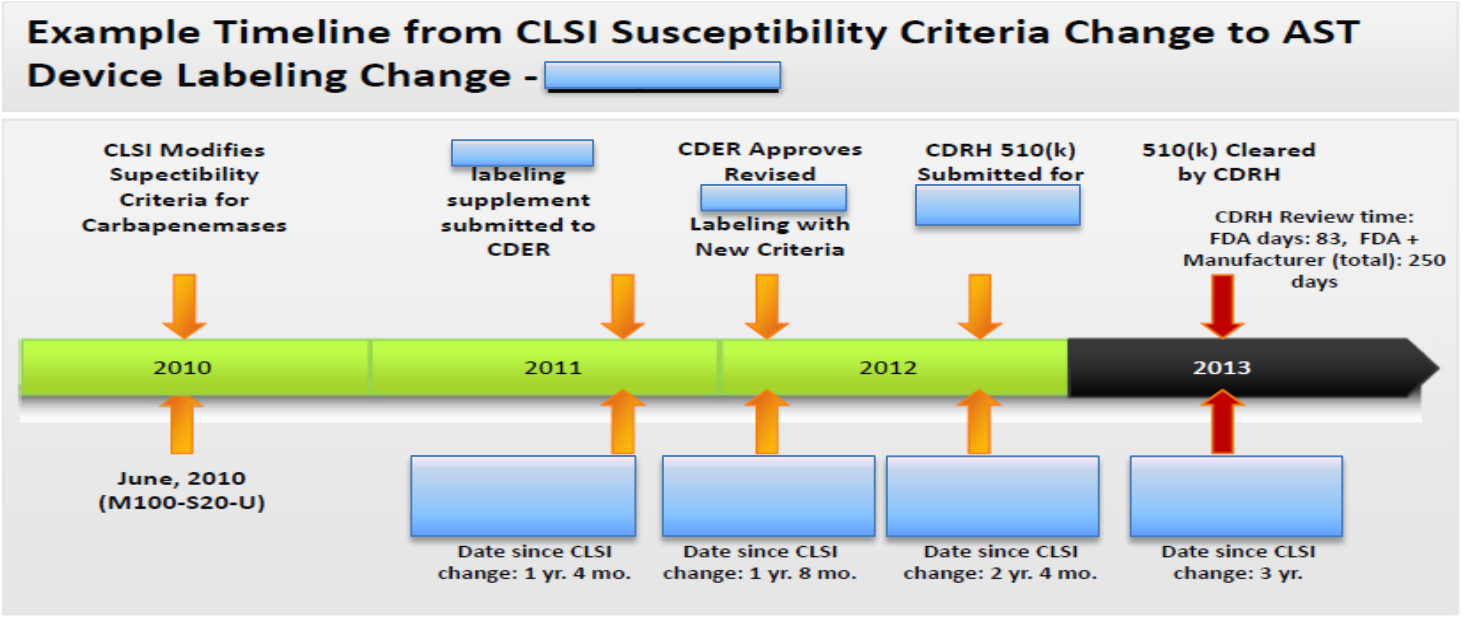
Device Development (2)

- Clearance of CRE molecular detection devices for infection control
- Support for new semantic interoperability standard for communicating device coding and for standardized Microbiology coding of laboratory tests (with CDC, NLM, ONC, other partners)
- Recent workshop on “Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices”
- New ‘breakthrough pathway’ for devices

Coordinated Development

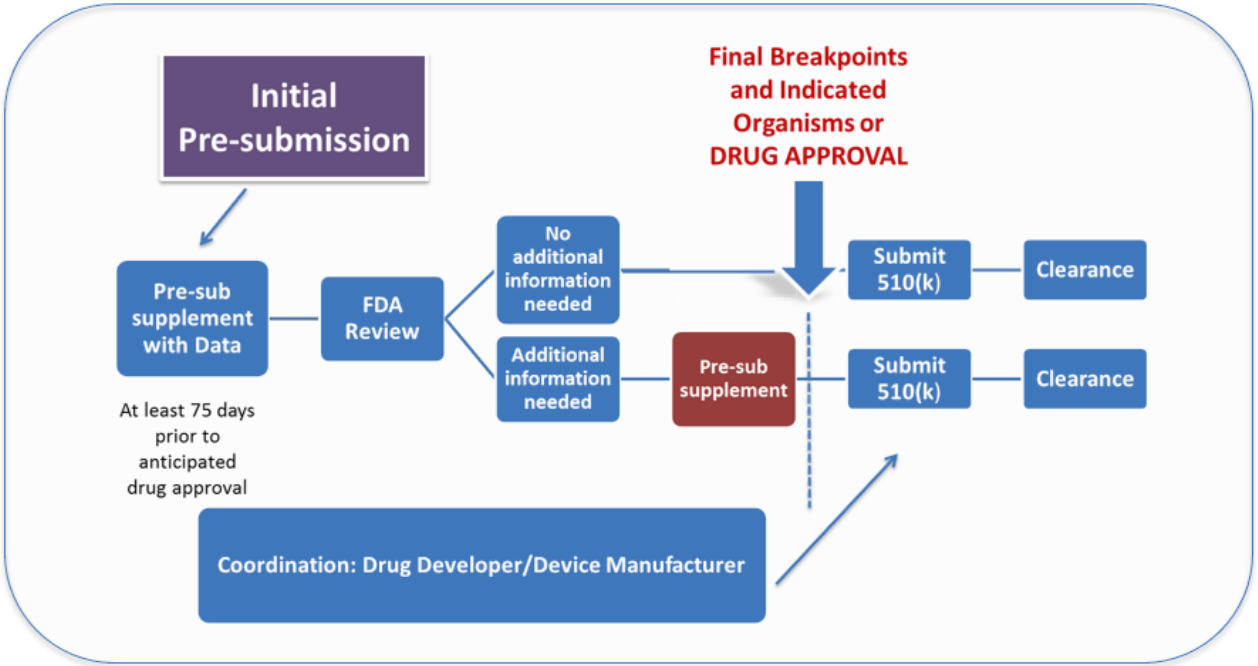
- FDA draft guidance addressing delays in making antimicrobial susceptibility test (AST) devices available at or near time of drug approvals published in September 2016
- Final guidance expected shortly
- Nine current pre-submissions

Prior to 21st Century Cures



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



Thank you.

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