# Challenges in Regulatory Considerations of New Diagnostics

**Committee on the Evidence Base for Lyme Infection-Associated Chronic Illnesses Treatment**

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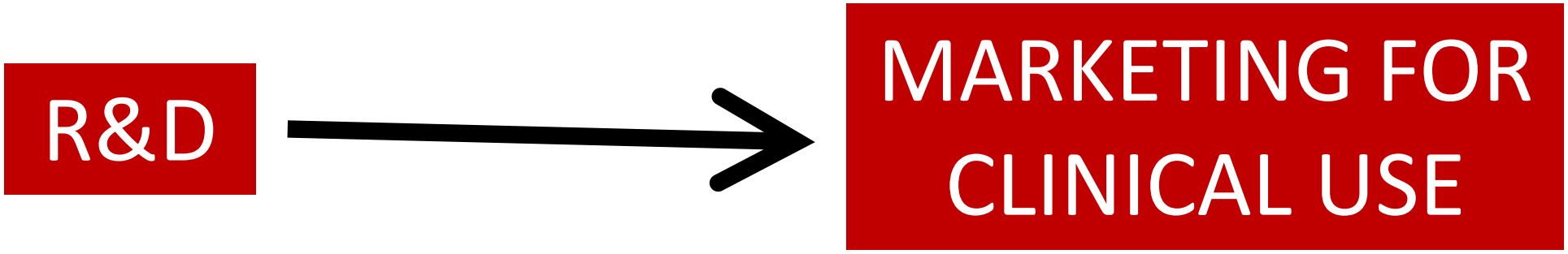
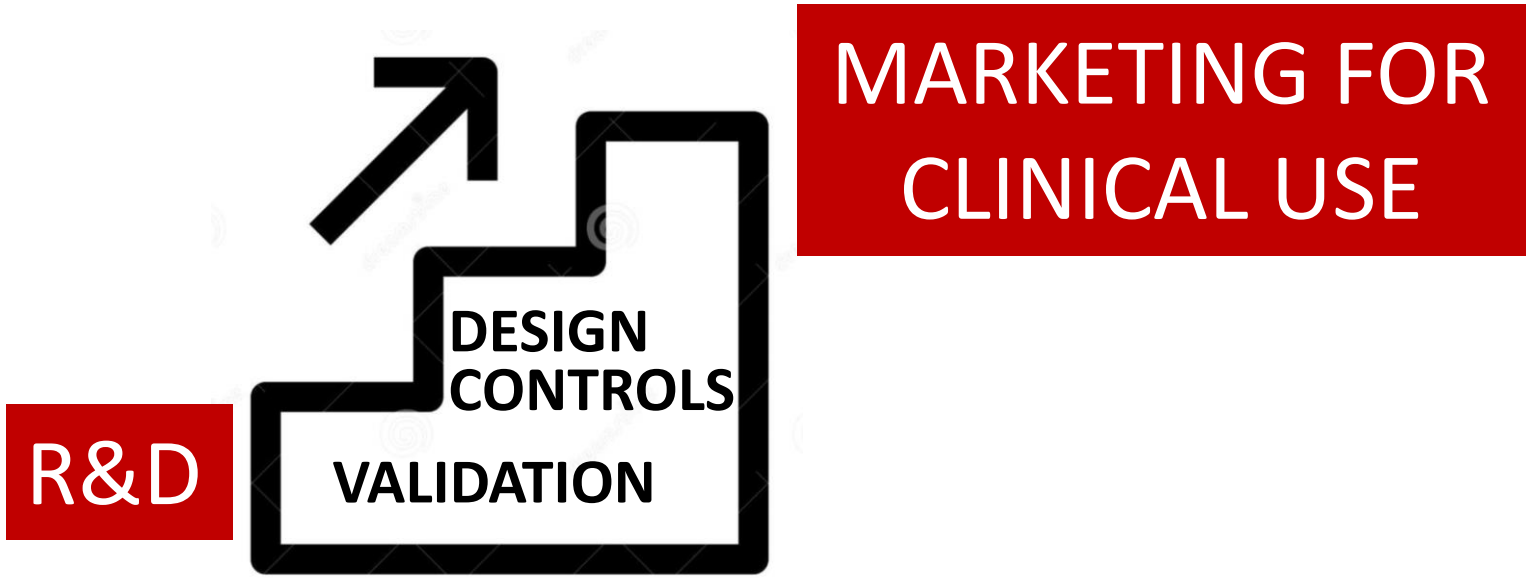
# Perception:  The Straight Line



# Reality: FDA Regulatory Requirements




**To assure that product is not:**

Misbranded - all claims are supported by data from well-controlled studies

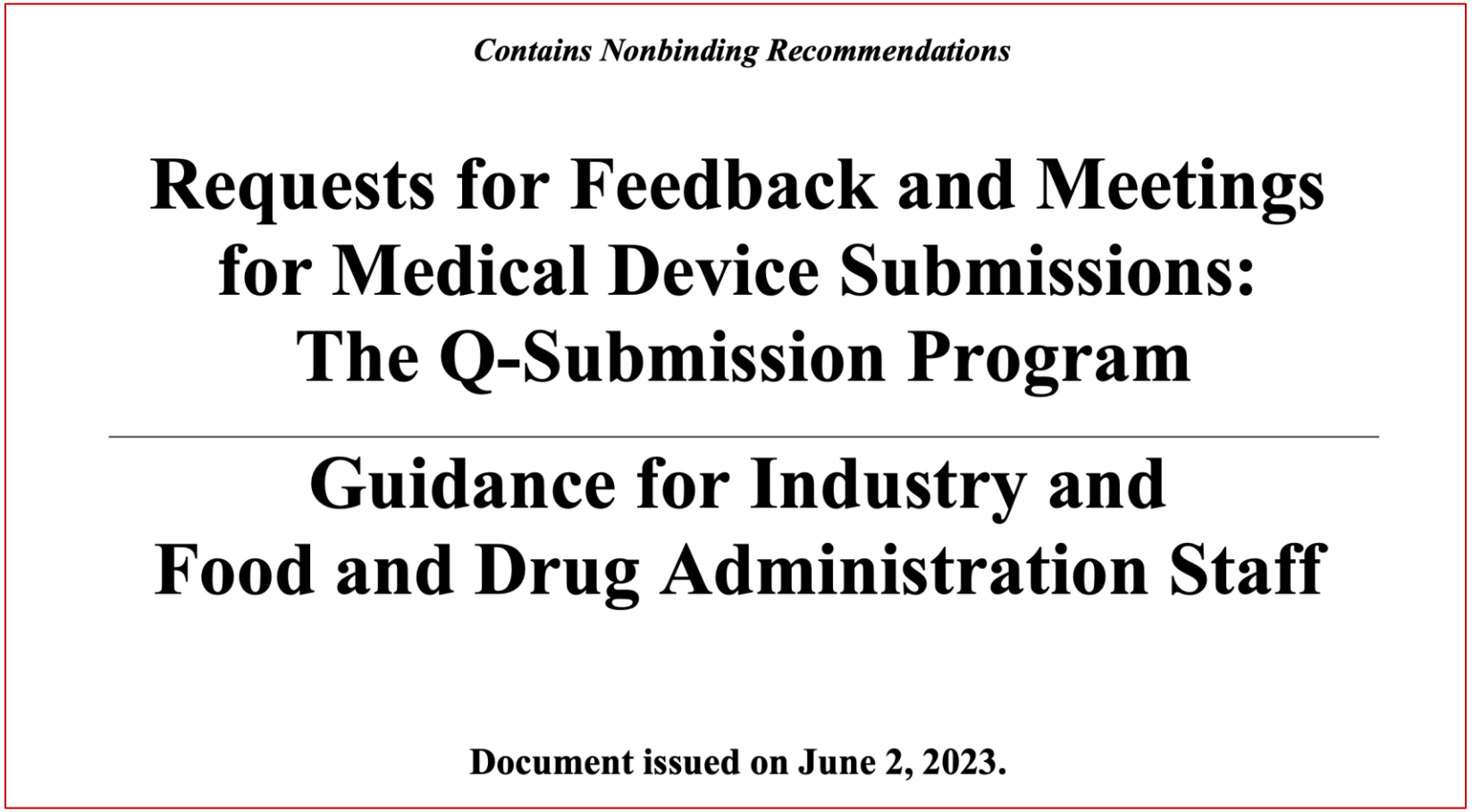
Adulterated - manufacturing process is under careful quality control

# Key Regulatory Concepts

- Start Design Controls where research ends and design begins, or after feasibility studies (basic research up to determining final test design).
- FDA is looking to see how well the test will perform in the hands of the intended users in the intended use setting.
- Eliminate bias as much as possible.
- Do the internal ”analytical”,  and particularly the external (clinical) studies, correctly the first time.
- Use a “locked down” device design in all studies.

# Key FDA Resources:

Get FDA input through the Pre-Submission process.



*Contains Nonbinding Recommendations*

**Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program**

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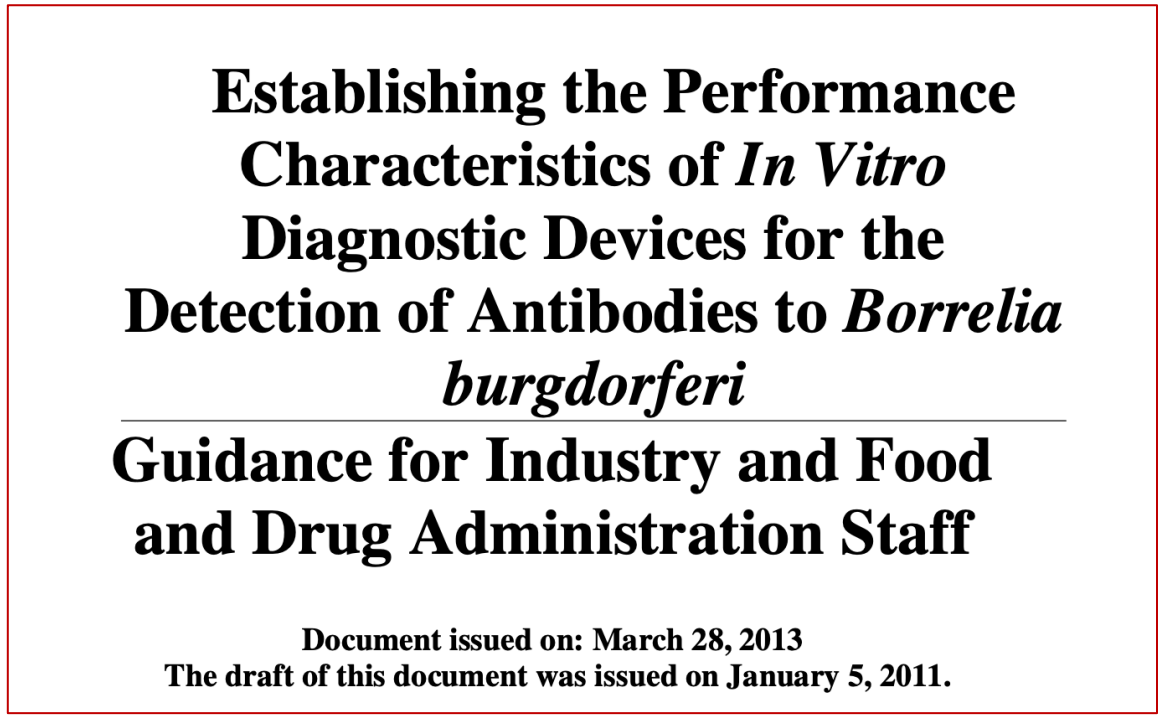
**Guidance for Industry and Food and Drug Administration Staff**

**Document issued on June 2, 2023.**

# Key FDA Resources:

Use FDA Guidance Documents and available precedent from prior FDA marketing authorizations to understand FDA's expectations



**Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi***

**Guidance for Industry and Food and Drug Administration Staff**

**Document issued on: March 28, 2013**
**The draft of this document was issued on January 5, 2011.**

**FDA clears new indications for existing Lyme disease tests that may help streamline diagnoses**

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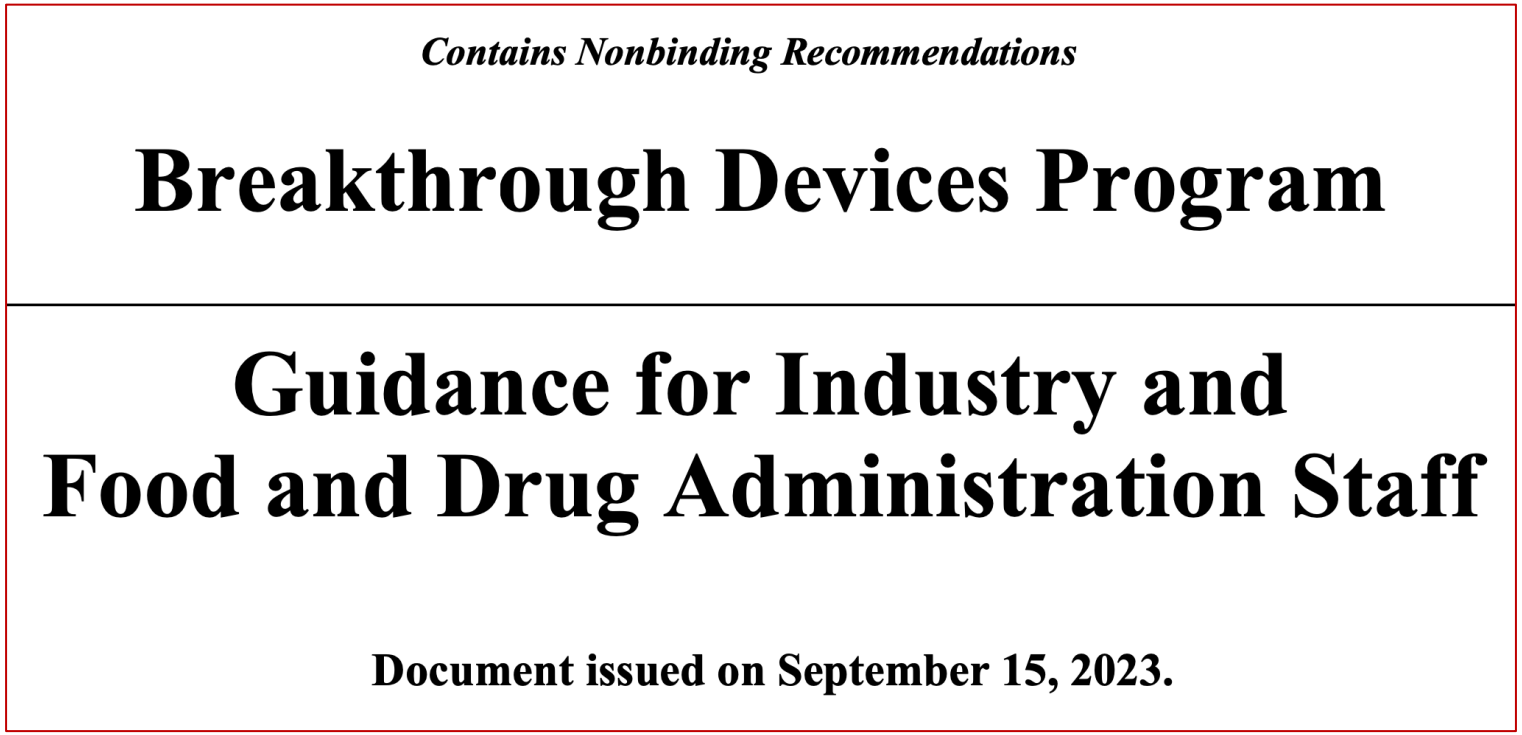
**For Immediate Release:** July 29, 2019

Today, the U.S. Food and Drug Administration cleared for marketing four previously cleared tests with new indications to aid in the diagnosis of Lyme disease. The tests cleared today are the first time that a test has been indicated to follow a new testing paradigm in which two tests called enzyme immunoassays (EIA) are run concurrently or sequentially, rather than the current two-step process in which a separate protein test called a Western Blot must be run after the initial EIA test.

# Key FDA Resources:

Fast-track review option for groundbreaking tests which will contribute to improving US public health



*Contains Nonbinding Recommendations*

**Breakthrough Devices Program**

**Guidance for Industry and Food and Drug Administration Staff**

**Document issued on September 15, 2023.**

# Challenges

- Lyme diagnostic tests are FDA Class II devices, requiring submission of a 510(k) document for review
- Must demonstrate equivalent or better performance than an existing cleared Lyme test

# Challenges

- How to handle a novel IVD that performs better than the current standard of care?
  - Challenge: To what should the new test be compared?
  - Clinical factor? *E.g.*, specimens with well characterized patient histories
  - Multi-Lyme test algorithms: Based on scientific rationale and with FDA concurrence

# Current Efforts