FDA/CDRH Office of In Vitro Diagnostic Devices

The Pre-IDE Process

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The #1 factor impacting review timeliness is

Quality of the Submission

An Overview

- Introduction
- Pre-IDE Process
  - Protocol proposal by sponsor
  - Review by FDA review team
  - Meeting with sponsor
  - Written feed back to sponsor
- Summary
- Question and answer period

Introduction

- What is a Pre-IDE?
  - A misnomer
  - A free consultative service by the review staff at the FDA
  - A non binding agreement between FDA & sponsor
  - Results in a well prepared submission
  - Results in a shortened review time
  - Results in saving research $$$

Pre-IDE Process

Protocol proposal (1)

- Introduction
  - A clearly stated intended use
  - Test principles
  - Device description

Intended Use Statement

- Should address the followings:
  - Qualitative or Quantitative
  - Testing matrix
  - Intended Population
    - Adult /Children/Age limitations
    - Asymptomatic--Screening
    - Symptomatic--Diagnosis
    - Already diagnosed--Monitoring
  - In conjunction with other diagnostics or stand alone test

Protocol proposal (2)

- Objectives of the clinical Study
  - To substantiate the proposed intended use
  - To establish the assay performance characteristics

Protocol proposal (3)

- Study Design--points to consider
  - A controlled comparative study to establish clinical performance of device compared to an established endpoint or surrogate
    - Clearly show how endpoints are defined
  - Patient samples should have inclusion and exclusion criteria

Study Design (continued)

- The number of patients/samples to be enrolled/used should be determined on sound statistical parameters
- Provide protocols for patient/sample information collection and documentation
  - How and by whom
- Consider having ≥ 3 clinical sites
  - provide contact information for all the PIs

Protocol proposal (4)

- Laboratory testing Procedures
  - Clinical labs performing the testing during clinical trial Should follow the procedure in the proposed product insert for both the comparetor and the test device
  - Specimen type should be defined
  - specimen collection, transport, process, and storage Should be defined
  - Quality control for the assay should be defined
    - frequency and trouble shooting

Protocol proposal (5)

- Study results
  - How results are reported to sponsor
  - How results are analyzed
    - Describe statistical tests
    - Describe how discrepant results are handled
  - Definition of true positive, true negative, equivocal, and inconclusive results for the purpose of establishing performance of the device

Protocol proposal (6)

- Regulatory & Administrative information
  - Study's start and finish dates
  - Obligations of the PI and sponsor
  - IRB & informed consent (non-US, Helsinki Accord)
  - Study site monitoring
  - SOPes for protocol deviation & change

Protocol review by FDA

- Review Team
  - Division team leader
  - Division review staff
  - Internal and external Consultant
    - CDER, CBER, CDRH, CVM, CFSAN, CDC, NIH...
- Internal FDA discussions
- Creation of consensus

Meeting with sponsor

- Face to Face
- Teleconference
- Videoconference

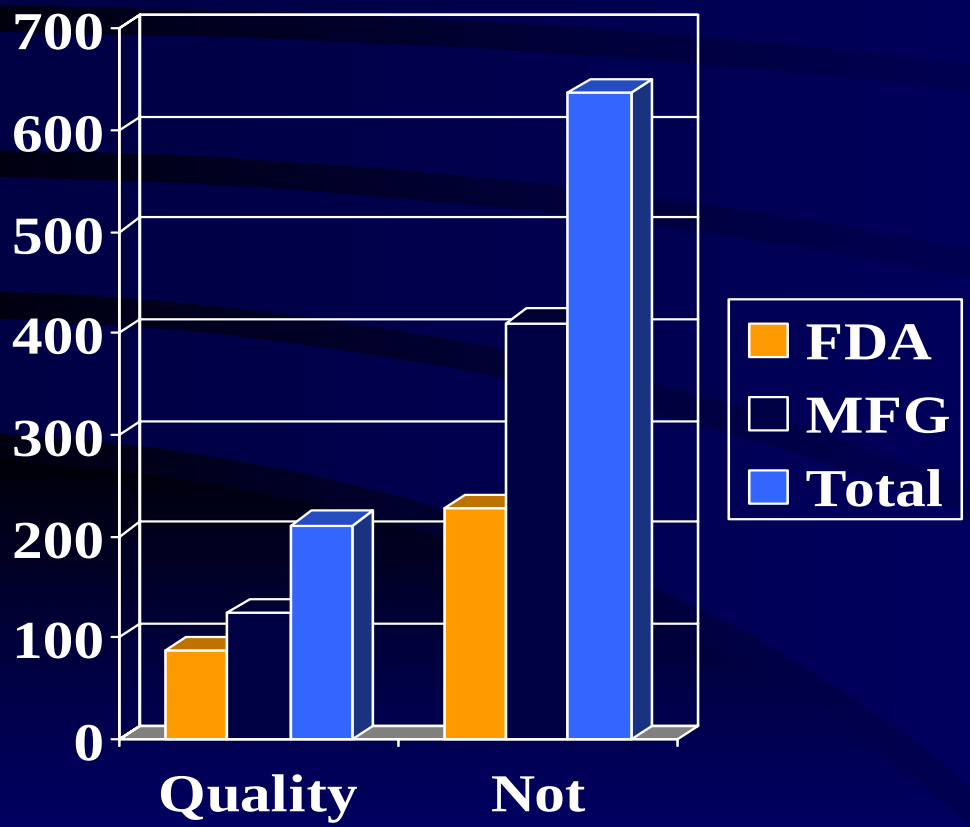
Written feed back

- E-mail
- Fax
- Mail

Summary

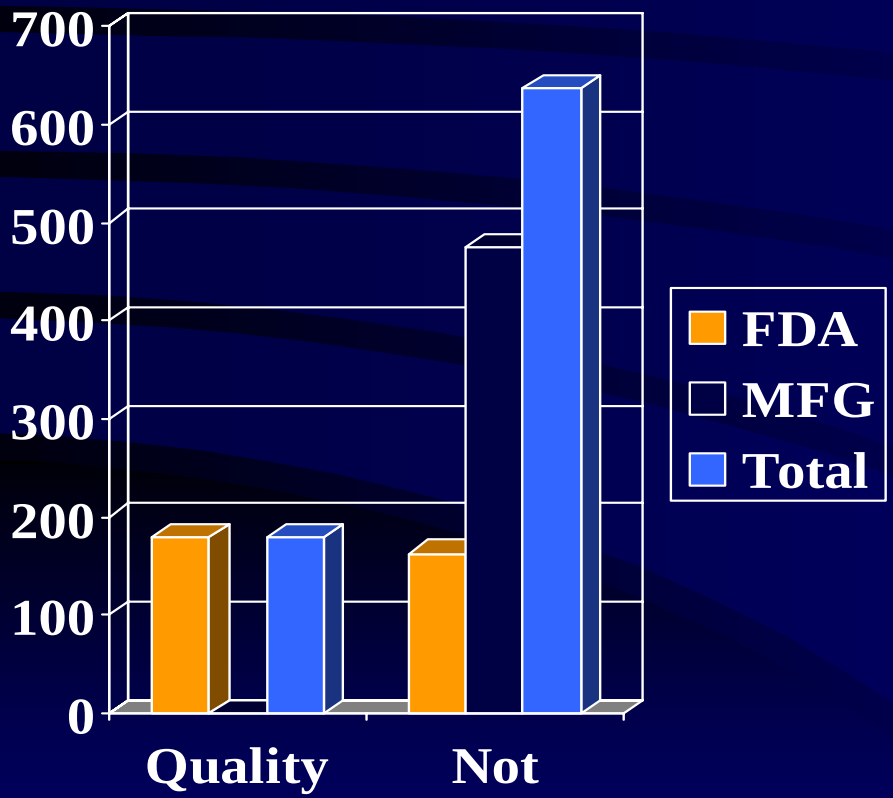
- The pre-IDE is
  - the current agency's thinking
  - extremely flexible framework for product development
  - does not bind the FDA or the sponsor
  - A streamlined method in which the FDA and the sponsor can agree on criteria and data necessary to insure safety and efficacy of device prior to start of preclinical and clinical trials → $$$$

Real-life Example

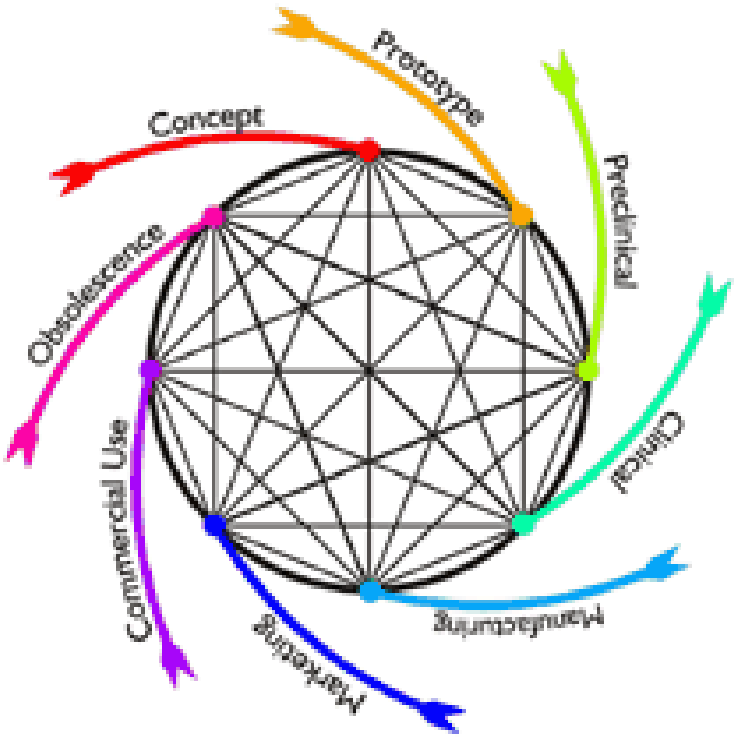


- Same device type
- Same branch
- Same reviewer
- Same timeframe
- different quality

Another Example



- Same as previous slide
- Quality Submission
- Right Studies
- Sponsor improvement



Ensuring the Health of the Public Throughout the Total Product Life Cycle -- It's Everybody's Business


Center for Devices and Radiological Health
CDRH