Least Burdensome Pathway to Market

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Least Burdensome Means to Market

- Required by §502 of FDA Modernization Act
- Applies to PMA, PDPs and 510(k)s
- Does not change standards for premarket review and approval or clearance

Definition of Least Burdensome

- An appropriate means of evaluating device effectiveness or demonstrating SE
- Has reasonable likelihood of resulting in approval
- Arrived at in consultation between FDA and submitter of premarket application
- Considered when seeking additional informaiton in a 510(k)

Least Burdensome:

Interpretation

- Goal
- To get the right information to support submissions -- not more, not less

Data

- Needed and appropriate to product

Process

- Interactive and transparent

Implementation

- Public comments via Jan. 1999 meeting with stakeholders
- Proposal from HIMA task force
- Comments via docket, letters, discussions
- Draft guidance released 9/1/1999
- Focus of this first guidance is on clinical data requirements

Least Burdensome is…

- A process not a decision
- An opportunity to
  - explore what data are available
  - determine what data are needed
- A time to ask questions

Guidance

- Gives general principles to identify least burdensome approach
- Does not give specific clinical data requirements for any device or type of submission
- Excludes in vitro diagnostic devices

Least Burdensome Guidance

- Provides FDA model for
  - assessing the need to develop new clinical data and
  - determining how to develop the necessary data
- Model is a consistent process approach to consider data requirements across all device types.
- Asks two global questions…

Least Burdensome Question 1

- Does available valid scientific evidence provide reasonable assurance that the device is safe and effective, or establish substantial equivalence to a predicate device, when used as indicated in the target population?

Least Burdensome Question I

Consider…

- The device and the use environment
- The indication and the claim
- Our current knowledge of the interaction of the disease / condition and the product
- Relevance and applicability of the clinical data

Least Burdensome Question 2

If the existing data, including the available clinical data, are not sufficient to answer yes to Question 1, then consider:

Question 2

- What is the most appropriate and reasonable way to obtain those data or Is a randomized controlled trial the least burdensome means to provide reasonable assurance that the device that the device is safe and effective or equivalent to a predicate?

Least Burdensome Question 2

Consider:

- Is a concurrent controlled study needed?
  - Potential sources for historical comparator data?
  - How can the comparison be made?
  - Potential biases or confounding factors to make use of historical data problematic?

Least Burdensome Question 2

- Is randomization necessary (i.e., is it the least burdensome design) to prevent /reduce bias, allow for direct comparison with an established device?
  - Study outcome measures
  - Duration of patient follow-up
- Other considerations of trial design
  - Method of analysis & reporting
  - Study monitoring
  - Post-approval potentials and needs

Least Burdensome Guidance

- A process model for determining the need for clinical data and the type of clinical data that are the least burdensome means to support successful premarket review
- Draft guidance is a first step in developing a useful process model -- hope others will test and refine it
- We encourage industry to draft "least burdensome" guidances for specific devices

Alternatives to FDA's Model

- Other processes for determining the least burdensome means are sure to emerge.
- No single right way
- Alternative approach proposed by HIMA task force
  - Require limited data until reaching a decision that less burdensome data cannot address relevant questions
  - FDA believes this approach would likely lead to delayed market entry and increased burden for both industry and FDA