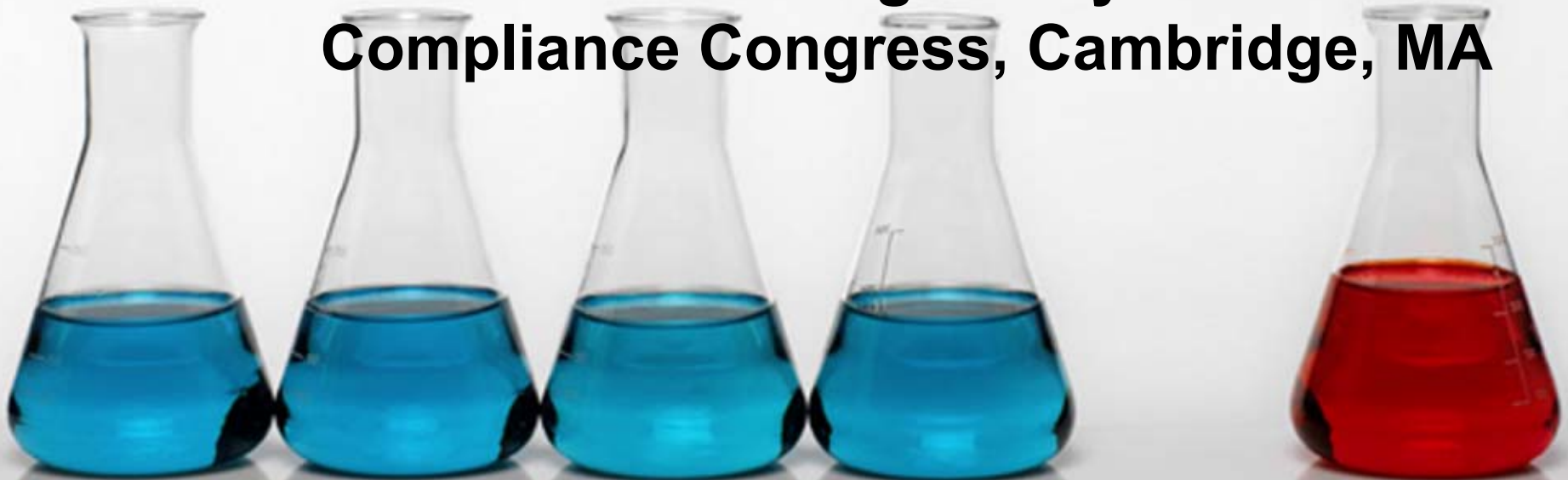




“Doing Double Duty”: A Corporate Perspective on Collecting Data for FDA and CMS in the Same Study

Barbara Calvert

Medical Device Regulatory & Compliance Congress, Cambridge, MA



March 30, 2006

Meeting FDA and Payer Data Requirements

Goal to obtain:

- FDA approval
- Coverage by public and private payers
- Adequate payment rates for new product/procedure

Do so in manner that is

- Timely
- Efficient
- Cost-effective

Topics for Discussion

Determining payer data requirements

Options for obtaining data-pros and cons

Interaction with FDA and CMS



Determining Payer Data Requirements

Analyze payer mix for new technology

Assess clinical and economic data requirements for all key payer groups

Determine data that is crucial vs. “nice to know”

Begin assessment of data needs early in development process

Determining CMS Data Requirements

Data to support coverage

- Early meeting with Coverage and Analysis Group to introduce technology, get initial feedback
- Share draft protocol and request detailed feedback
- Document CMS concerns/recommendations in writing
- Maintain ongoing dialogue

Determining CMS Data Requirements

Data to support adequate payment

- Analyze relevant payment systems
 - Special requirements for new technology payment (e.g. hospital inpatient new tech “add on” payment, hospital outpatient “pass-through” payment, New Tech APC payment)
 - Implicit data needs
- Consider collecting charge data in trial to support adequate hospital payment

Determining Private/Other Payer Data Requirements

Conduct survey of selected payer medical directors

Seek advice of physician advisory boards

Retain specialized consulting firm to conduct assessment

Independent “third party” critique of draft trial protocol

Determine Data That Is Crucial vs. “Nice To Know”

Assess “make or break” issues for coverage

- Lack of Medicare aged patients
- Lack of “long-term” outcomes data
- Wrong or inadequate control group
- Perceived major trial design flaw

Cost effectiveness data

- Increasingly important for coverage and payment
- Include economic study in all pivotal trials

“Double Duty” Options for Obtaining Data for Payers

Collect data in pivotal IDE trial for FDA approval

- Pro-Timely and efficient
- Con-Could slow down/complicate FDA approval

Collect data in FDA required post-approval study

- Pro-Separate from FDA approval, more efficient than conducting separate study post approval
- Con-Data not timely

Conduct separate parallel IDE trial

- Pro-does not affect FDA approval, timely data
- Con-Not efficient, FDA IDE approval uncertain

Non “Double Duty” Options for Obtaining Data for Payers

Conduct separate trial post FDA approval

- Pro-Does not affect FDA approval
- Con-Not timely or efficient

Model/extrapolate from existing data

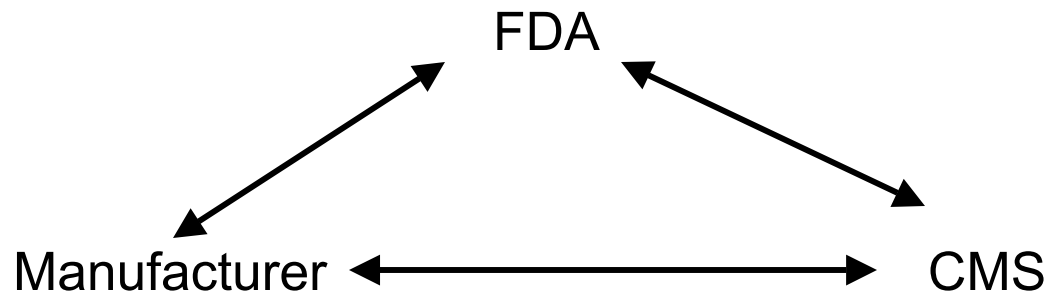
- Pro-does not affect FDA approval, less expensive
- Con-Less rigorous

Possible to use different methods to obtain different data elements

Interaction with FDA and CMS

FDA-CMS coordination required for all “double duty” options

Manufacturer should drive and manage ongoing 3-way communications



- Organize joint FDA-CMS calls/meetings
- Document agreements in writing

Interaction with FDA and CMS

Manage sharing of data

- Authorize FDA to share some/all data with CMS
- Share FDA reports/data directly with CMS
- Document in writing data to be shared, how it will be used
- Confirm that proprietary data will be protected

Be creative in suggesting new ways to meet FDA/payer data needs



 **Abbott**
A Promise for Life

 **Abbott**
A Promise for Life