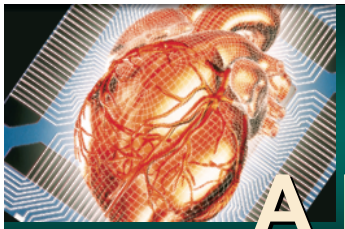
Food & Drug Administration Amendments Act of 2007

Implications for Publication Planning Professionals and Biomedical Publications

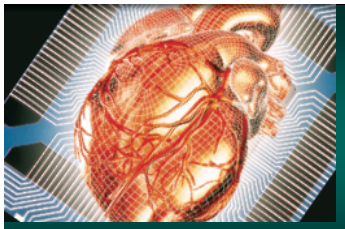
DISCLAIMER: The content of this presentation may not accurately reflect current legal or regulatory requirements, industry standards, or professional best practices. ISMPP is providing access to this presentation as a member service only, and does not recommend or condone the use of this presentation in whole or in part to support legal or professional decisions or practices.



Title VIII-Clinical Trial Databases:

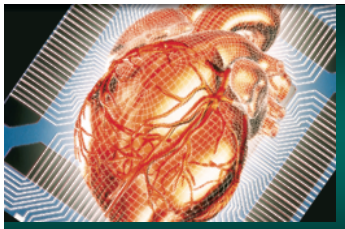
A Perspective from an Academic Trialist

Kenneth A. Jamerson M.D.
Professor Cardiovascular Medicine
Medical Director, Program for Multicultural Health
University of Michigan Health Care System



OBJECTIVES

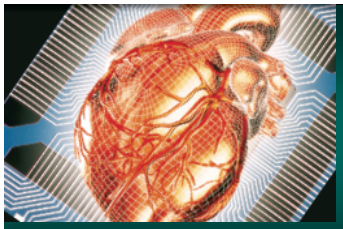
- Explore some of the implications of Title VIII on clinical trial conduct at academic centers
  - Examine the Impact of this legislation on the reporting of trial results
  - Address potential impact of title VIII on the academic progress of faculty and their training programs



The Academic Mission
Patient Care, Research, and Teaching

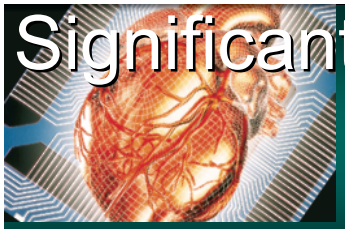
- Title VIII calls for:
  - Timely and consistent reporting of clinical trial initiation, progress, and results.

Pros: Recruitment of better informed patients
Enhance refinement of protocols
Innovation in research design and study questions
Sponsors may better manage resources
The option of obscuring or failure to report negative trials is greatly reduced



Characteristics of AASK Participants

Characteristics	Percent of Participants
Age	60.1 yrs
Gender	58% male
Income (annual)	9,500
Education	11 yr
Divorced	56%
Employment	36%
Insurance	28%
Concurrent problems	3.8



Significant Variables in the Decision NOT to Participate in Biomedical Research

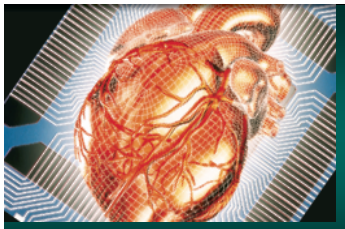
Experimented on	**45/29**
Side effects	**53/16**
Interfere with Tx.	**46/16**
Time concerns	**37/21**

Most important factor in Decision not to participate

-health concerns: 42%

-suspicions: 21%

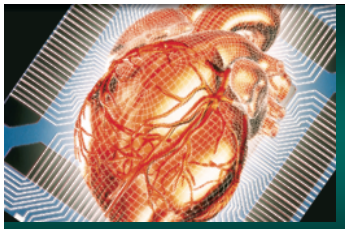
Kind of help which might lead them to participate, more information



The Academic Mission
Patient Care, Research, and Teaching

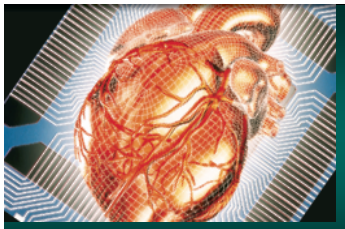
- Title VIII calls for:
  - Timely and consistent reporting of clinical trial initiation, termination, and results.

Pros: Recruitment of better informed patients
Enhance refinement of protocols
Innovation in research design and study questions
Sponsors may better manage resources
The option of obscuring or failure to report negative trials is greatly reduced



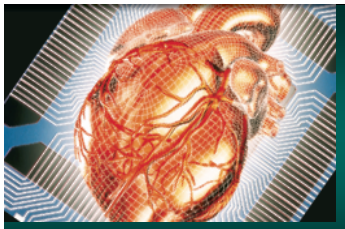
Data Elements of Title VIII

- Design and outcomes
- Patient disease state, and entry criteria
- Individual site status
- Updated recruitment status
- (above with in 21 days of protocol activation)
- Efficacy and safety data
- Other data?
- (later with in 1 year of trial end)



Data Elements of Title VIII Provide a Landscape for Clinical Trails

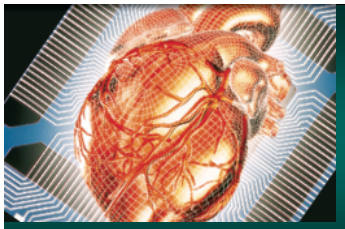
- Clinicaltrials.gov
  - Repository for trial designs, timelines, patient populations under study, and research questions!
  - Parenthetically providing the underpinnings for trial innovation



The Academic Mission
Patient Care, Research, and Teaching

- Title VIII calls for:
  - Timely and consistent reporting of clinical trial initiation, progress, and results.

Pros: Recruitment of better informed patients
Enhance refinement of protocols
Innovation in research design and study questions
Sponsors may better manage resources
The option of obscuring or the (lethargy) failure to report negative trials is greatly reduced

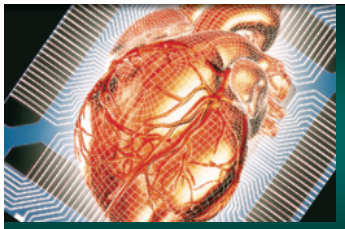


The Academic Mission
Patient Care, Research, and Teaching

- Title VIII calls for:
  - Timely and consistent reporting of clinical trial initiation, termination, and results.

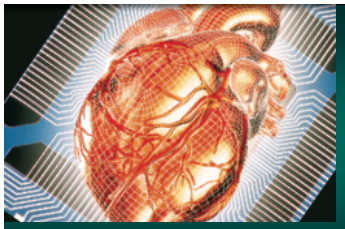
Cons:

The timelines can erode the academic mission
Premature public data basing can interfere with peer review
Timelines in Title VIII are too aggressive
"Other data" is needlessly vague



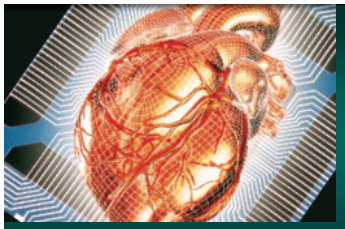
Timelines for Reporting Clinical Trials proposed in Title V III

- Data elements: AE's, Primary and Secondary outcomes



Timelines for Reporting Clinical Trials proposed in Title V III

- End of trial: proposed end of study, or actual end (date of last patient visit)
  - Publications usually begin with data base lock (AE collection is 30 days after LPLV).
    - *Major message may be safe but secondary messages may be compromised*
      - Time, opportunity, and resources for training are severely limited-Academic mission compromised!

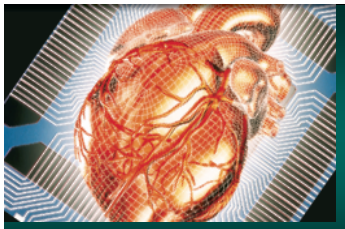


Timelines for Reporting Clinical Trials proposed in Title V III

Major message may be safe but secondary messages may be compromised. (6 months)

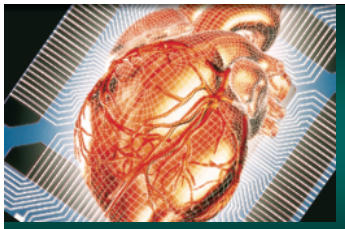
Multi-center trials are organized by committees, writing groups, nationally and globally

(LIFE has > 150 publications)



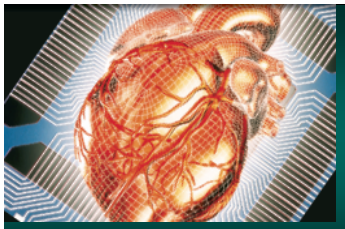
Timelines for Reporting Clinical Trials proposed in Title V III

- Time, opportunity, and resources for training are severely limited with out the ability to perform the secondary (hypothesis generating) analyses
- Academic mission compromised!
  - Students and trainees lose opportunities for original reports



Other Data Elements and Assurance That Data are not Mis-leading

- Inherently this infers re-interpretation of the data. This is process needs clear elucidation. (done with experts?)
  - How is conflict resolved?
  - How does one reconcile Title VIII review with the peer review process?
  - Are there parameters for other data request?

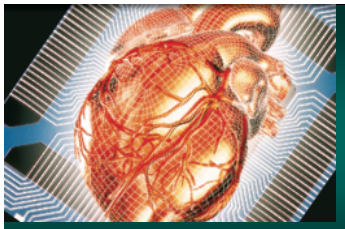


SUMMARY

- Title VIII calls for:
  - Timely and consistent reporting of clinical trial initiation, progress, and results.

Title VIII will provide more access to data (for the segment of the population performing web searches).

But hinders the academic mission by truncating time for exploratory analyses, opportunities for training, and modifying peer review (super review).



CONCLUSIONS

Liberalizing reporting timelines (data base lock rather than last patient visit) would diminish the impact on Academic Centers.

The NIH director has the option of prolonging timelines and liberal rulemaking privileges over the next 3 years.

Food & Drug Administration Amendments Act of 2007

Implications for Publication Planning Professionals and Biomedical Publications