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Impact of the 2007 FDA Amendments Act (FDAAA) on Data Disclosure at GSK

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Agenda

- GSK Status prior to new law
- FDAAA 2007 Effective 27th September 2007
  - Protocol posting
  - Additional Proposed Changes from NIH
  - Results posting
- GSK's actions

Protocol Posting Key Points

- **“20 elements”**
- **FDAMA 113 Requirements**
- **WHO, ICMJE Requirements**
- **Phase I-IV trials**
- **Delays in fields granted with CMO approval (<0.5% of protocols)**

Results: GSK CTR

- Policy and Design Started in 2003
- Site design finalized and implemented in 2004
- Provides an easily accessible repository of results from GSK-sponsored clinical trials
- Supplements communications in:
  - Approved prescribing information
  - Journals, scientific meetings, healthcare professional letters
- Access to the register is unrestricted
- Provides links to published materials
- Also automatically posted to PhRMA site

GSK CTR
Study Results Posting Program

- All trials of marketed products completed since the formation of GSK in Dec 2000
  - Phase 1-4 results (>3000) posted for approved products (82)
  - Pre-marketing trials of new formulations when they provide important safety information relevant to marketed formulations
- Summaries of studies for marketed products completed before Dec 2000 if they are likely to inform medical judgment
- Post-approval studies are posted within 10 months of completion
  - In rare instances, there may be a posting delay if:
    - GSK seeing intellectual-property protection
    - Issues with journal publication policies

GSK CTR

- GSK posts ICH-E3 formatted study summaries and lists associated publication citation
- Summaries are scientific and non-promotional
- If it has not been possible to publish a study 1 year after posting to the register a conclusion will be added to the study summary
- External compliance oversight has been implemented

GSK Clinical Trial Register 3 Years On – 2007 Website Hits

Month	Web Site Hits
Jan	26,595
Feb	25,312
Mar	27,926
Apr	27,238
May	36,064
Jun	31,750
July	31,776
August	27,648
September	22,767
October	24,026
November	20,482
December	18,019

FDAAA 2007 Changes: Protocols

- Scope controlled clinical trials
  - Includes expanded access programs

- Change in information required
  - Lay summary of the study
    - Current “purpose” statement may be sufficient.
  - Intervention name and Intervention type
  - Expected completion date***
  - All:
    - primary and secondary outcome variables
    - Inclusion/Exclusion Criteria
  - Individual site recruiting status

FDAAA 2007 Changes: Protocols

Timing

- **All new fields for studies required by FDAMA 113 studies to be posted by 90 days post enactment (26th Dec 2007) or within 21 days of first patient enrolled**
- **All information for other studies to be posted with one year of the enactment**

Additional Fields that *may* be required by NIH*

- Why Study Stopped?
- Number of Arms **- Definition: Number of intervention groups (enter 1 for single-arm study).**
- Masking
  - *Masking Roles –
- Enrollment - **Number of subjects in the trial. Anticipated and Actual**
- Collaborators
- Expanded Access Status
- Primary and Secondary Outcome Time Frame - **Example: within the first 30 days (plus or minus 3 days) after surgery**
- Arm Number or Label **- the number, letter or name used to identify the arm. Examples: A, 2, III**
  - Arm Type **-**
- Intervention Description **- include dosage form, dosage, frequency and duration.**

*To be resolved by Sept 2008

FDAAA 2007 Requirements: Results

- **Trials in scope:**
  - **Studies that support an efficacy claim**
  - **Studies conducted after approval linked to protocol posting**
  - **May ‘require’ studies conducted 10 years before enactment be posted to ‘protect public health’**

FDAAA 2007 Requirements: Results

Basic results data set for trials of US approved medicines within 1 year of enactment:

- **Table of demographic and baseline data overall and for each arm**
  - **to include number who dropped out and number excluded from the analysis**
- **Primary and secondary outcome measures and table of values for each arm including results of statistical tests**
- **Linked to the protocol register entry of these outcomes**
- **Point of contact for scientific information about the clinical trial results**
- **Whether there is an agreement between the sponsor and principal investigator that restricts the PI from discussing the trial results at public/private fora or to publish in a journals**

FDAAA 2007 Requirements: Results

Adverse Events:

- **No later than 18 months after enactment the Secretary to determine the best method for including serious and frequent adverse events in a manner and form that is useful and not misleading**
- **If the Secretary fails to issue the regulation within 24 months of enactment the following additional elements will be included:**
  - **Table of anticipated and unanticipated SAEs grouped by organ system with number and frequency in each arm**
  - **Table of anticipated and unanticipated AEs that are not SAEs that exceed the frequency of 5% in any arm, grouped by organ system with number and frequency**
  - **Plus information to enhance patients' understanding and to ensure such tables do not mislead patients or the lay public**

FDAAA 2007 Requirements: Results

Expanded data set for trials of US approved medicines - not later than 3 years after enactment:

- **Non-technical summary for patients (if Secretary determines that they can be included without being misleading or promotional)**
- **A technical summary (if Secretary determines that they can be included without being misleading or promotional)**
- **The full protocol** or **such information on the protocol for the trials as may be necessary to help evaluate the results**
- **Such other categories as the Secretary determines appropriate**
- **Consideration of expanding to treatments not approved by FDA.**

GSK Actions

- **Working closely with NIH**
- **Involved in PhRMA various work streams**
- **Preparing for other new requirements**

New GSK CDR

- Protocol and results posting
- Searchable
- Two phases of delivery
  - Phase 1 compatible with protocol posting requirements and current CTR summaries
    - March 2008
  - Phase 2 to include results
- Direct links to e-Track to avoid copying information
- Will have workflow to facilitate writing and review
- Posting to external sites to be managed by third party
- Our vendor is will keep new website current

Summary: Issues

(number stars relates to complexity)

- **Completion Date*****
- **“Observational Studies”****
- **Site Recruiting Status***
- **Early Phase Trials: GSK Policy vs compliance with the legislation***
- **Expanding scope to unapproved therapies***