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Disclosure of Clinical Trial Results: Obligations and Industry Practices

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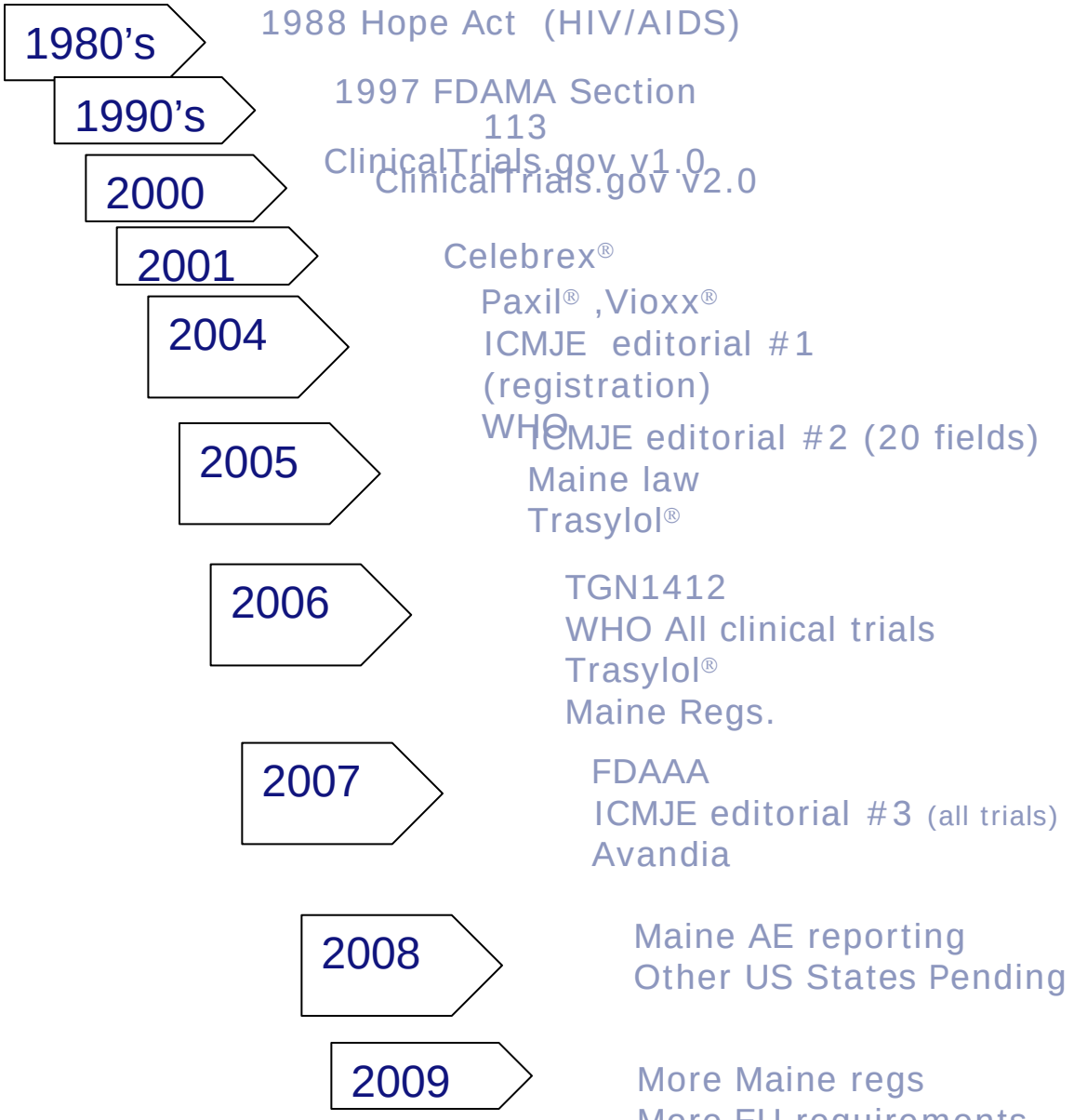
A Short History for Clinical Trail Disclosure



Increasing Foreign Registry Requirements

How Did We Get Here?

- Inconsistent reporting of protocols, results
- High-profile legal action against large pharma
- Lack of transparency of all stakeholders (industry, gov't agencies, journals)
- Changing landscape of regulations

FDAAA Title 8 Basics (1)

- Registry milestones
  - Trials in serious, life-threatening conditions
    - Ongoing trials: **27 Dec 2007**
    - New trials: within 21 days of FPFV
  - All other applicable trials
    - Ongoing trials: 27 Sept 2008
    - New trials: within 21 days of FPFV

FDAAA Title 8 Basics (2)

- Results milestones
  - Basic results required by 27 Sept 2008
    - Demographic, baseline characteristics
    - Primary, secondary outcomes
    - Point of scientific contact
    - Contractual restrictions of investigators ability to discuss results
  - Serious adverse event, frequent adverse event required by 27 Sept 2009

FDAAA Title 8 Basics (3)

- Expanded results rules expected by 27 Sept 2010
  - Lay and technical summary of results?
  - Posting trials of unapproved drugs?

- US Public Law 110-85 (FDAAA)
  - (http://prsinfo.clinicaltrials.gov/fdaaa.html)

Latest and Greatest: Maine

- Adopted revised regulations
  - Released 29 October 2009
  - **Came into effect 02 November 2009**
- Previous regulations different from FDAAA (e.g., adverse event reporting)
- New regulations more in line with FDAAA (i.e., similar field requirements)

New Maine Regulations (1)

- Applicable clinical trials
  - Phase II-IV
  - Off-label uses
  - Observational
  - Post hoc analyses
  - Bioequivalency trials of a drug against the innovator drug or biological product, or against another drug or biological product

New Maine Regulations (2)

- Trial conducted outside the US that
  - have ≥1 sites within the US or its territories
  - results have been/are intended to be submitted to/held for inspection by FDA as part of research/marketing application
  - sponsor relies upon results for marketing/ promotional claims or educational efforts/ materials to prescribers/consumers in Maine

New Maine Regulations (3)

- Trials exempt from new regulations
  - –Protocols **registered** before Jan. 1, 2010
  - –Results *submitted* before Jan. 1, 2010
  - –Observational trials completed before Jan. 1, 2010

New Maine Regulations (4)

- **Any discontinued clinical trial**
  - **Must be registered by latest of**
    - 21 days after patient enrollment begins
    - first date drug/bio product is dispensed, administered/delivered/promoted in Maine for any indication
  - **Must post results by latest of**
    - 1 year (+ applied extensions) after trial completion
    - first date drug/bio product is dispensed, administered/delivered/promoted in Maine for any indication

New Maine Regulations (5)

- All post hoc analyses with significant deviation/ correction of previous results of interventional trials are subject to new regs
- Data field requirements now closely mirror FDAAA/ClinicalTrial.gov requirements
- Must complete all mandatory data elements and all other relevant (“optional”) data elements (if data available)

New Maine Regulations (6)

- **Links/citations to all articles by any of the trial investigators published in peer-reviewed medical journals summarizing safety/efficacy**
- Sponsors have 120 days after adoption of new regulations to post information
- Prescription Drug Clinical Trial Reporting - Final Rule (www.maine.gov/dhhs/boh/clinical-trials-reporting-final.doc)

Ex-US Clinical Trial Disclosure (1)

- Article 57(2) of Regulation (EC) No726/2004
  - Relates to Phase II-IV adult clinical trials in EudraCT
- Article 41 of Regulation (EC) No1901/2006
  - Relates to **all** paediatric clinical trials
- Submissions (sometime in 2010)
  - Both: protocol information submitted at CTA; made public immediately at CTA approval
  - Paediatric results submitted within 6 months of trial completion; adults within 1 year of trial completion; both: made public immediately after submission

Ex-US Clinical Trial Disclosure (2)

- Many registries/results databases are populated by the health authorities/ regulatory agencies
- 21+ mandated ex-US registers
- 13+ voluntary ex-US registers
  - Many now may require native languages

Where Do We Go From Here?

“Such other categories as the Secretary determines appropriate”?

Information Resources

- DIA Clinical Trial Registry/Results Database Working Group
  - Meets ~1st Tuesday every month
- NIH/ClinicalTrials.gov staff

Contact Information

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