



Industry Update on Results Disclosure

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TIPPA Midwest Chapter Meeting

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Agenda

- History and current Clinical Trial Disclosure landscape
- Corporate Governance of Processes
- Publication Planning



Acronyms

- **AAMC:** Association of American Medical Colleges
- **CTR:** Clinical Trial Registry
- **FDAMA:** Food and Drug Modernization Act
- **FACT Act:** Fair Access to Clinical Trials Act
- **ICMJE:** International committee of Medical Journal Editors
- **IFPMA:** International Federation of Pharmaceutical Manufacturers and Associations
- **IOM:** Institute of Medicine
- **NIH:** National Institutes of Health
- **PhRMA:** Pharmaceutical Research and Manufacturers of America
- **WHO:** World Health Organization
 - **ICTRP:** International Clinical Trials Registry Platform



Goals of Clinical Trial Disclosure

- ❑ Provide information sufficient for patients to enroll in clinical trial
- ❑ Enhance accountability and transparency of clinical trial information
- ❑ Provide access to results of clinical trials in a comprehensive and objective manner
- ❑ Improve industry reputation



Clinical Trial Disclosure Landscape

Inputs

PhRMA AAMC IFPMA AMA Ottawa Grp Countries

FDAMA-113 NIH Congressional Acts ICMJE IOM WHO-ICTRP States

clinicaltrials.gov
clinicalstudyresults.org

Users

Recruitment
(Patients, doctors)

Journal
Editors

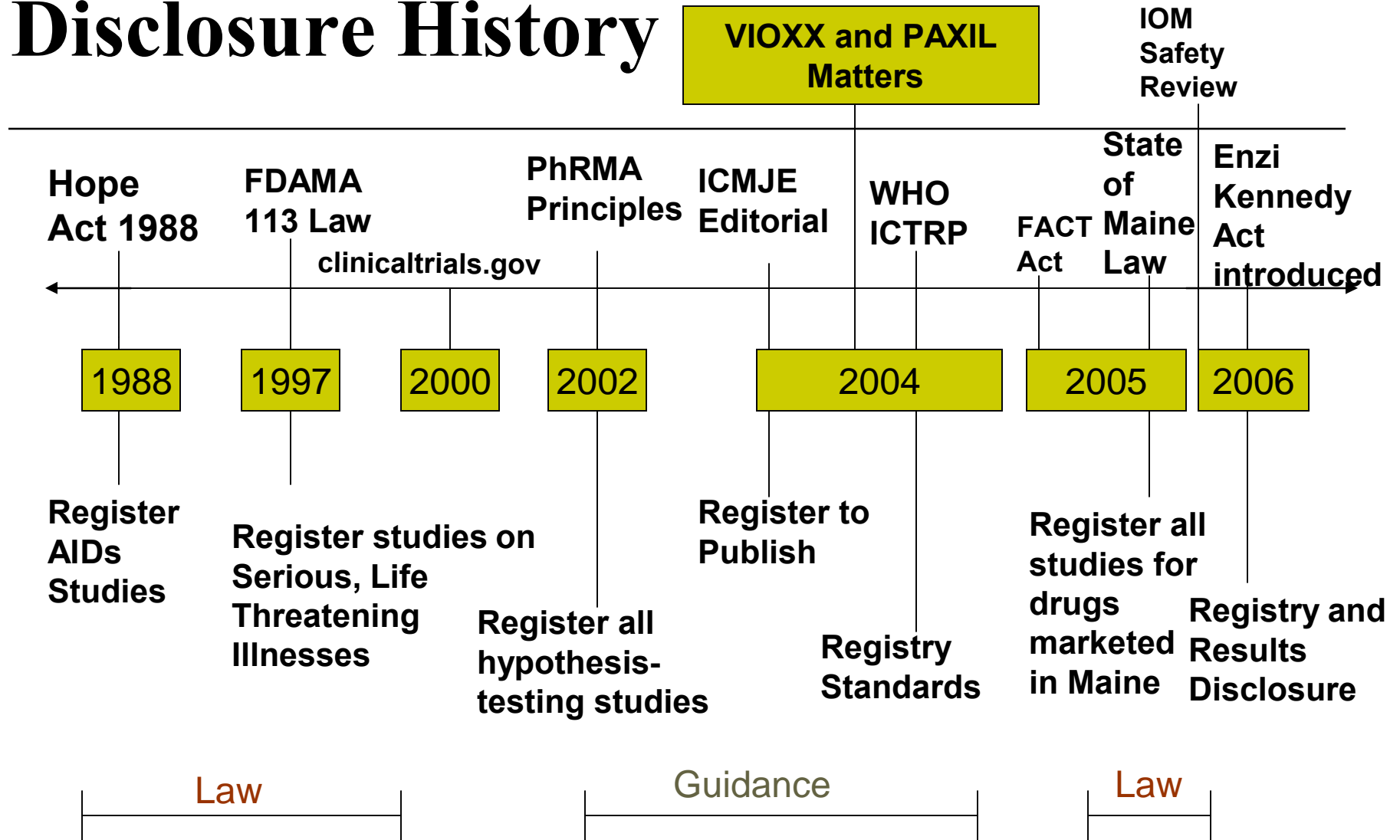
Researchers
& Funders

Consumer
Advocates

Health
Policy
Makers

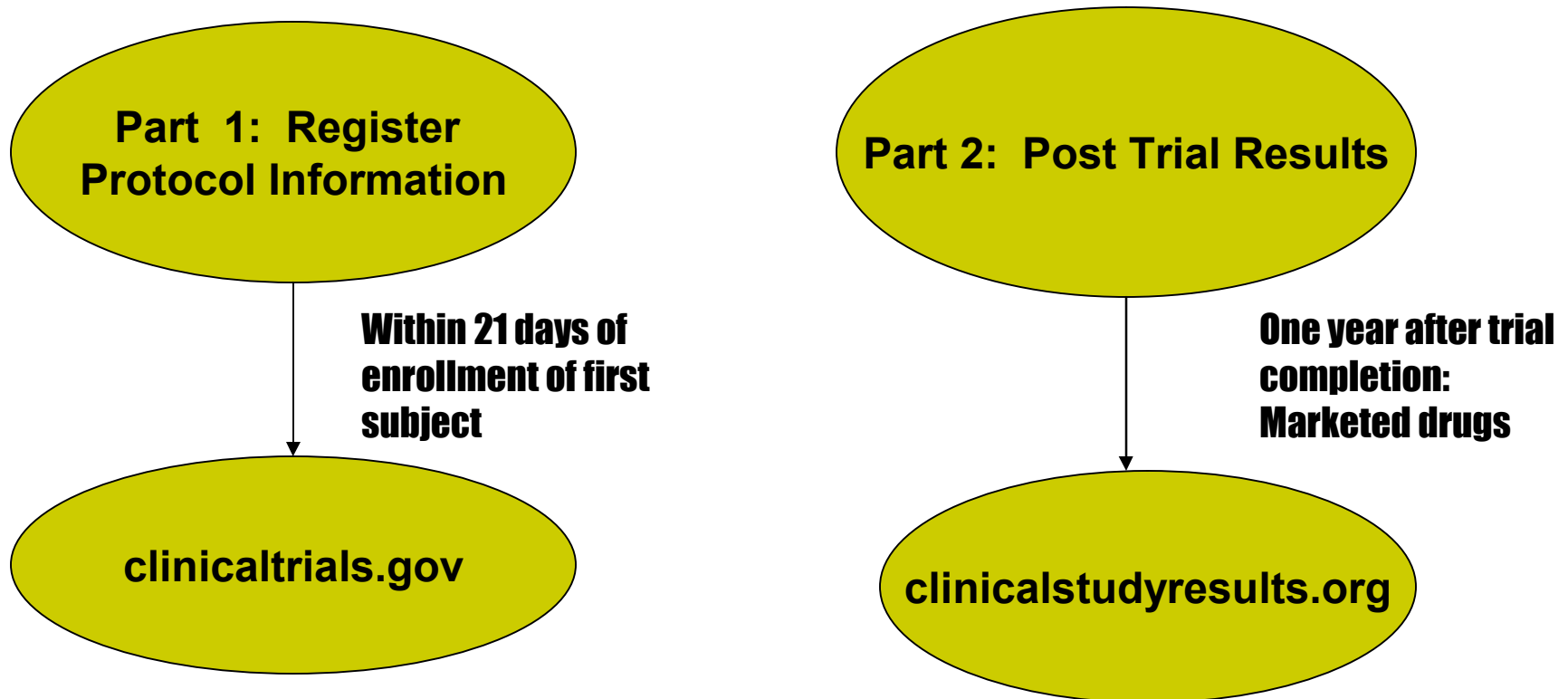
Systematic
Reviewers
(Cochrane,
Oregon)

Disclosure History



Public Disclosure of Study Information

Clinical Trial Life Cycle



Current Disclosure Law/Guidance

□ Registration

■ Law

- FDAMA 113
- State of Maine

■ Guidance

- ICMJE
- PhRMA
- IFPMA
- WHO

□ Results Disclosure

■ Law

- State of Maine

■ Guidance

- PhRMA
- IFPMA



State Legislation Status

- **2 States enacted Clinical Trial Disclosure legislation: Maine and Virginia**
 - Comments on Maine Regulations submitted

- **At least 13 States considering legislation: CT, NJ, RI, MI, MD, MO, CA, HI, TN, MS, OK, IL, MN**





Law: State of Maine

- ðBeginning October 15, 2005, a manufacturer or labeler of prescription drugs dispensed in Maine that employs, directs or utilizes marketing representatives in Maine shall disclose its clinical trials and information concerning results of clinical trials on a publicly-accessible website.ö
- ðMaine law applies to trials of prescription drugs conducted or sponsored by the manufacturer on or after October 15, 2002.ö

Results Disclosure Requirements: Law

Organization	Disclosure Definition	Disclosure Timing	Information To be Disclosed
State of Maine Law	Post on a publicly accessible website -trial information -results of the trial including Adverse events.	Post information on any clinical trial that the manufacturer conducted or sponsored on or after Oct. 15, 2002.	for prescription drugs dispensed in Maine that employs, marketing representatives, disclose its clinical trials and results conducted or sponsored on or after 10/15/2002.
State of Maine Regulation (Not yet enacted)	Post results on a publicly funded Internet website, or if not available, a publicly accessible Internet website	Trials initiated on or after October 15, 2002. Premarketing: Post results by the date it is marketed in the state. Postmarketing: Post within 1 year after trial completion. May delay up to 12 months if analysis is not sufficiently complete to post. Deadline may not exceed 24 months in total.	Information concerning results of each completed or discontinued covered clinical trial: -ICH E3 study summary -Link or citation to publications -Link to labeling -Aliases of the product

Results Disclosure Requirements: Guidance

Organization	Disclosure Definition	Disclosure Timing	Information To be Disclosed
PhRMA	<p>Peer reviewed publication preferred.</p> <p>Abstract submission or a poster or oral presentation at a scientific meeting or making results public by some other means.</p>	<p>Within one year of trial completion for marketed products only.</p> <p>May delay posting results up to one year after announcement of intent to publish.</p>	<p>Results of all hypothesis testing studies regardless of the results.</p> <p>Elements of the database:</p> <ul style="list-style-type: none"> -link to drug label -Peer review publications -ICH E3 synopsis of studies not published
IFPMA Joint Position	<p>Post results of all clinical trials other than exploratory on a publicly accessible database regardless of trial outcome.</p>	<p>Disclose within one year after the drug is marketed and commercially available in at least one country.</p> <p>Post-marketing: register within one year of trial completion.</p>	<ul style="list-style-type: none"> -Post publication citation or ICH E3 study synopsis on a publicly accessible website. -Disclose results for failed product if it has significant medical importance.



Corporate Guidance: Points to Consider

- Consider clinical trial “Life Cycle”
- Determine internal and external stakeholders
 - Law/guidance to be followed
 - Functional areas to be considered
- Set up Advisory Committees and process teams
 - Guidance from functional areas
 - Buy in
 - Set reasonable goals
- Communicate Timelines
- Train functional areas



Key Internal Stakeholders

- Clinical Operations
- Information Systems
- Legal/IP
- Marketing
- Medical Affairs
- Medical Writing
- Pharmacovigilance
- Public Affairs
- Publications
- Quality
- Regulatory Affairs
- Record OP Center
- Therapeutic Area
- Statistics
- Senior Management
- Others????

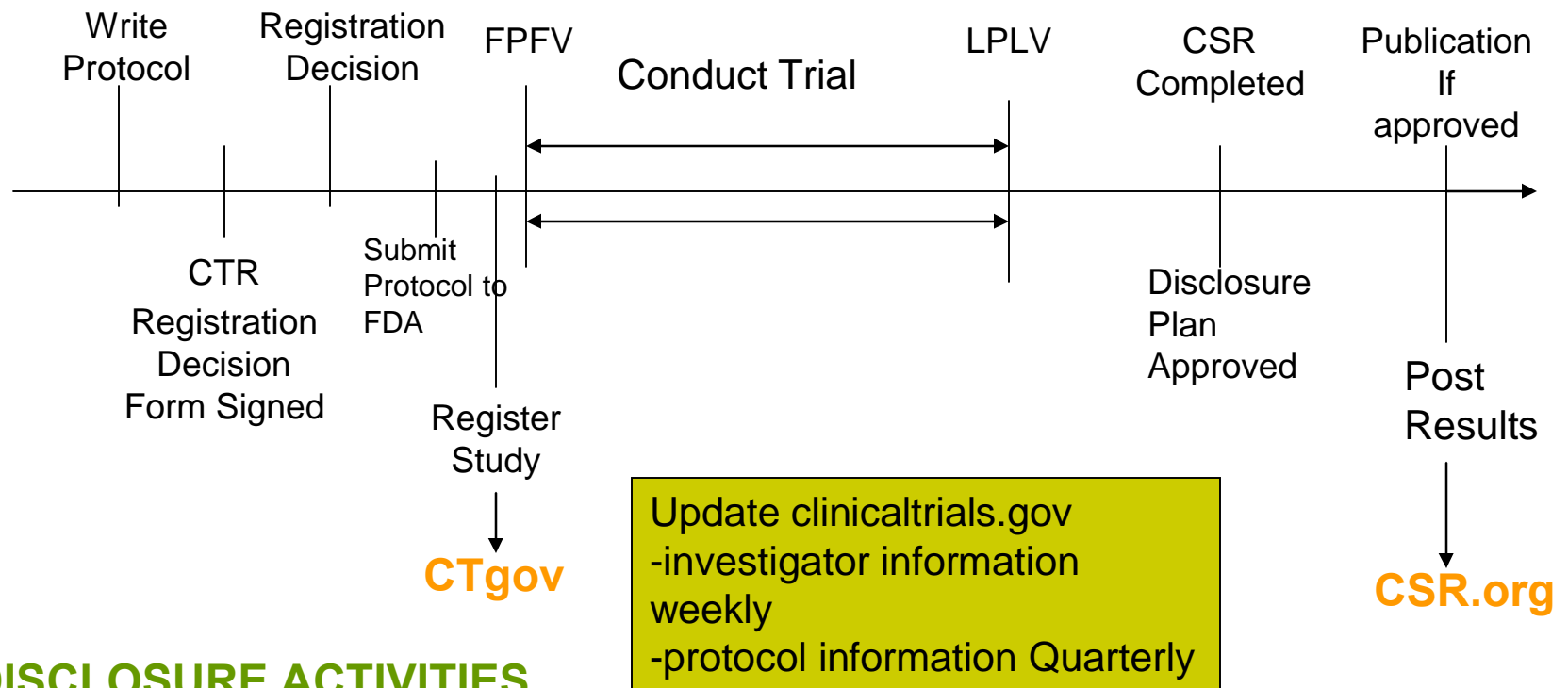


Key External Stakeholders

- FDA
- ClinicalTrials.gov
- PhRMA
- IFPMA
- ICMJE
- WHO
- Patients and Physicians
- Others as on "Landscape" slide

Clinical Trial Life Cycle

TRIAL ACTIVITIES





Publication Planning: Points to Consider

- ❑ Clinical trial timeline should consider all functional area needs (entire life cycle)
- ❑ Set up communication between Registry/Posting Staff and Publication Team
- ❑ Complete all activities as early in the trial life cycle as possible
 - Publication Plan (choice of authors, journals, etc)
- ❑ Publication Team should be included in results discussion meetings
- ❑ Posting may affect ability to publish in some journals



Publication Planning: Points to Consider (2)

- ❑ Publication content should match protocol/plan
- ❑ Deadlines should be tracked; automatic reports desirable
- ❑ Consider the audience
- ❑ Consider having a disclosure governing board to review and approve disclosure plan
- ❑ Consider posting disclaimers on the posting and individual documents



Group Discussion

- As you implemented results disclosure rules into your publication plan:
 - Did you account for information sharing between the registry/posting and publication staff?
 - Did Posting may affect ability to publish in some journals?
 - What challenges did you face?
 - What lessons did you learn?



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