

Operationalizing Global Clinical Trial Disclosures

Summary

- According to US Law, responsible parties must register **protocols** and disclose **results** of applicable clinical trials in a public registry (ClinicalTrials.gov).
- Yet compliance is poor with most studies (~78%) still not reporting results.
- Federal requirements are in the process of being revised, and penalties for non-compliance will soon be enforced.

Challenges for Sponsors

- Managing a complex workflow with multiple lifecycle stages
- Evolving regulatory requirements/mandates
- Consistent global reporting (17 countries with mandatory laws and unique registries)
- Strict guidelines makes data difficult to summarize
- Decentralized workflow lacks efficiencies that can impact quality and compliance

Why Report Clinical Trials?

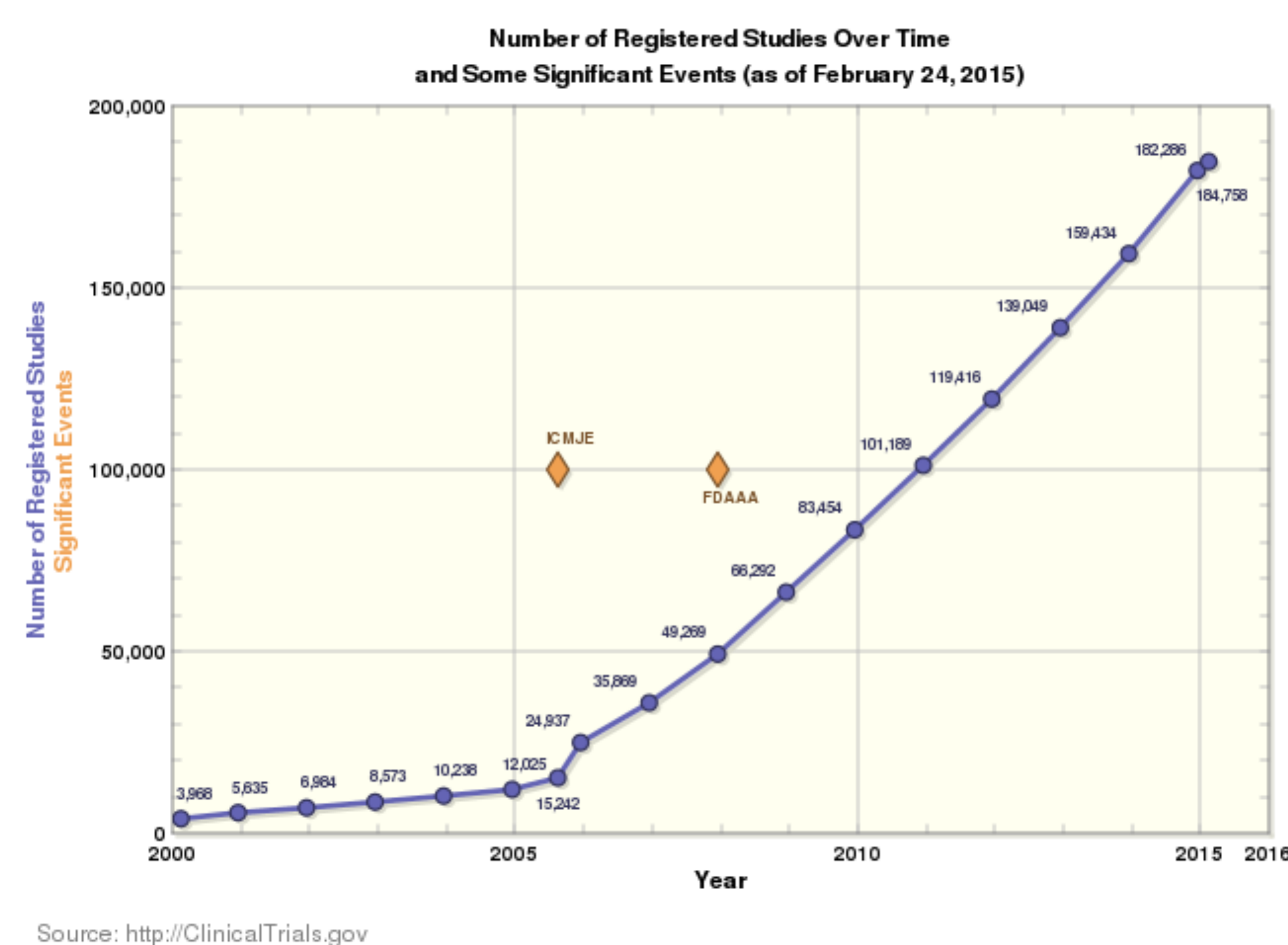
- Mandated by Laws
- Limits publication bias
- Removes redundancy in testing by ensuring accountability of trial conduct and results, regardless of a positive or negative outcome
- *“The registration of all interventional trials is considered to be a scientific, ethical, and moral responsibility.” –World Health Organization*

Penalties for Non-Compliance

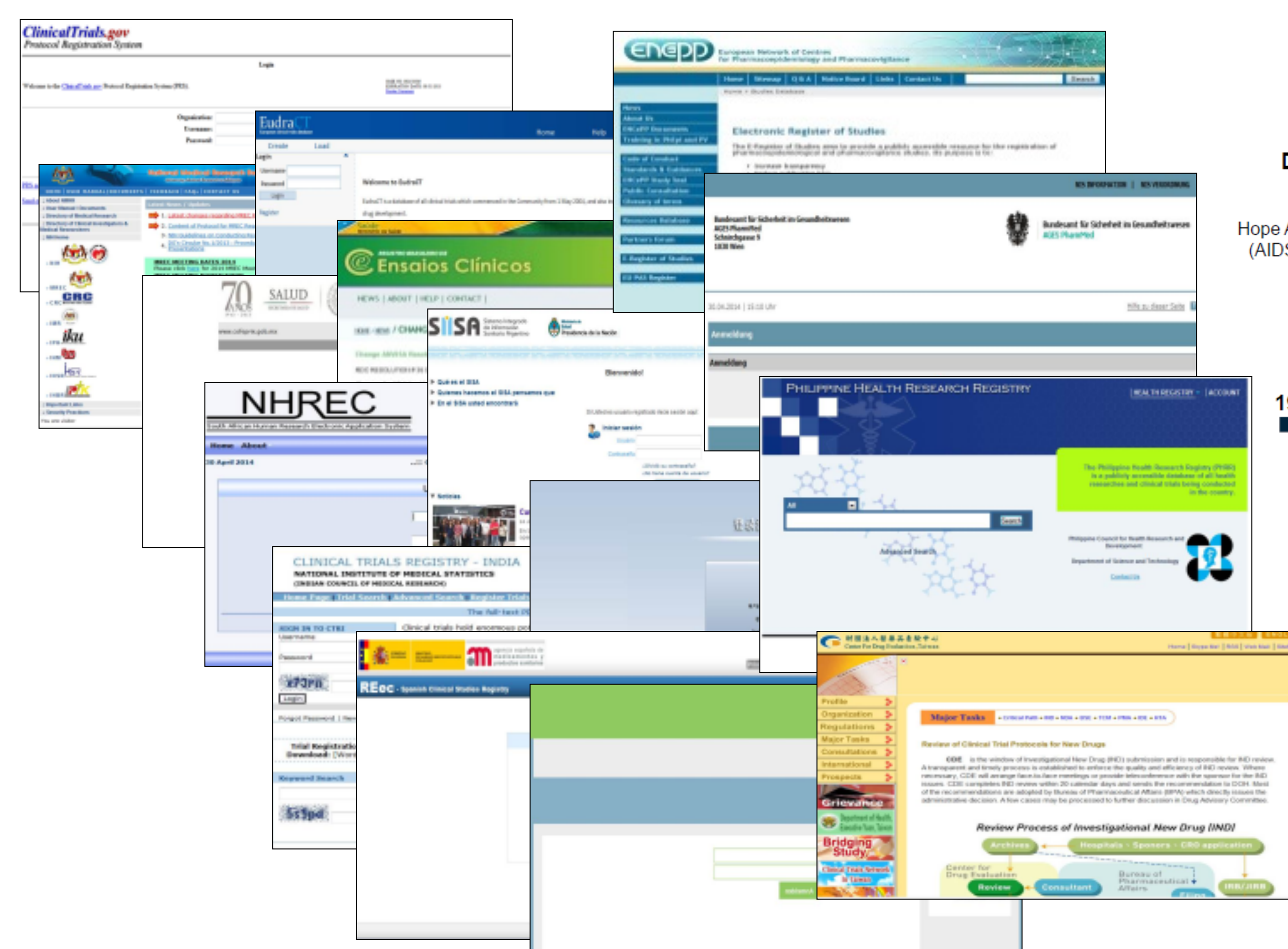
- Federal fines up to \$10,000 per day
- Withholding of NIH or other government funding
- Scientific journals may refuse publication
- Stricter enforcement upcoming
- U.S. House of Representatives expressed concerns to FDA about noncompliance, citing studies
- Health and Human Services delegated enforcement responsibility to FDA in 2012

Expansion of Disclosure Requirements

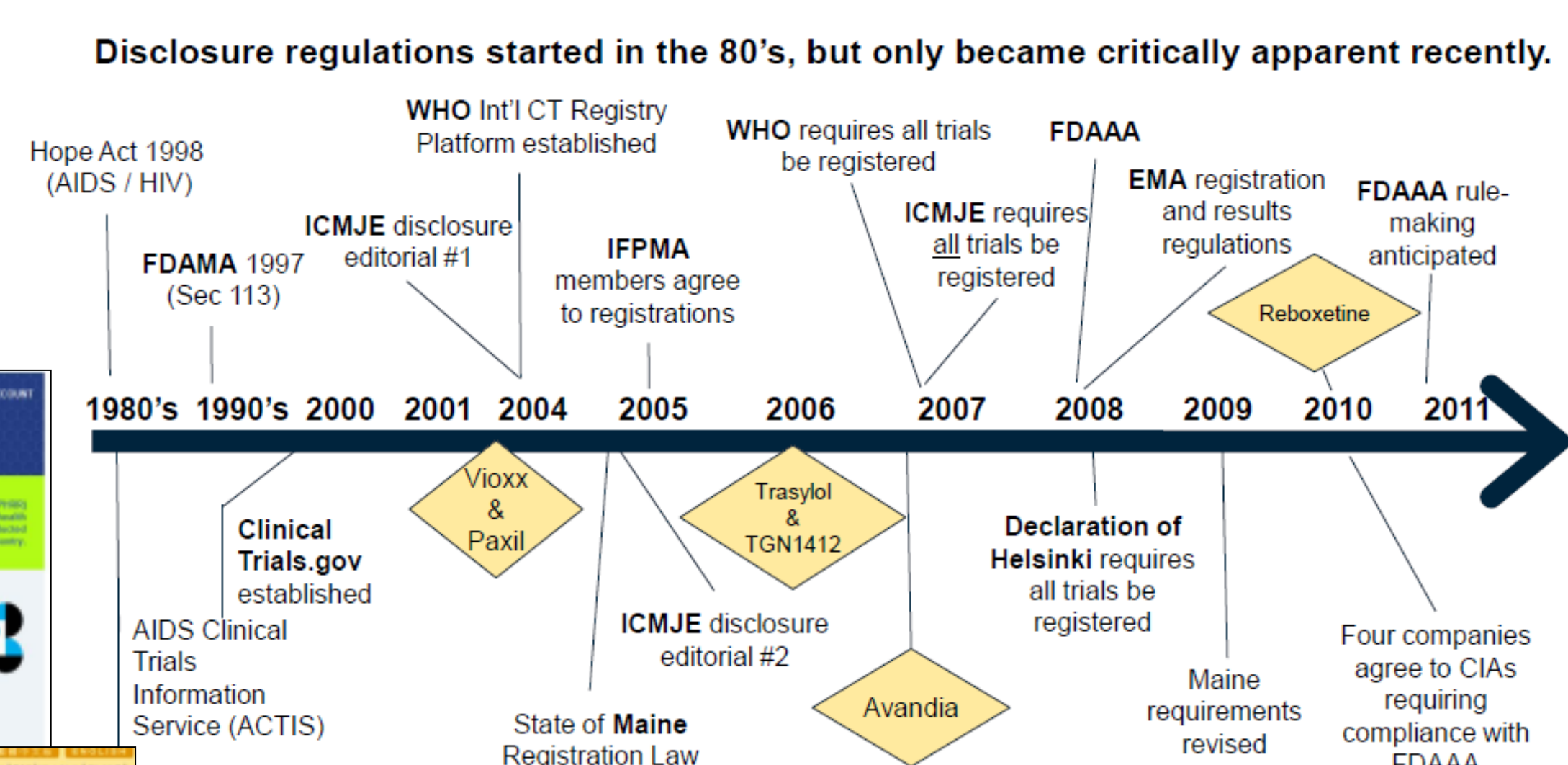
More Protocols and Results Being Reported



More Countries Involved



More Regulations



The Solution

A Transparency Tracker with an Integrated Lifecycle Workflow Dashboard that aligns workflow steps with requirements specific to Lifecycle stages.

- **10-step workflow...**
 - **sequenced over 6 lifecycle stages...**
 - **with over 75 touch points per study per country...**
 - **a pipeline dictating a steady flow of studies with different stages of activity and reporting periods...**
 - **across 6 functional areas**

