

Clinical Trial Transparency: Organizing to serve the public interest



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Agenda

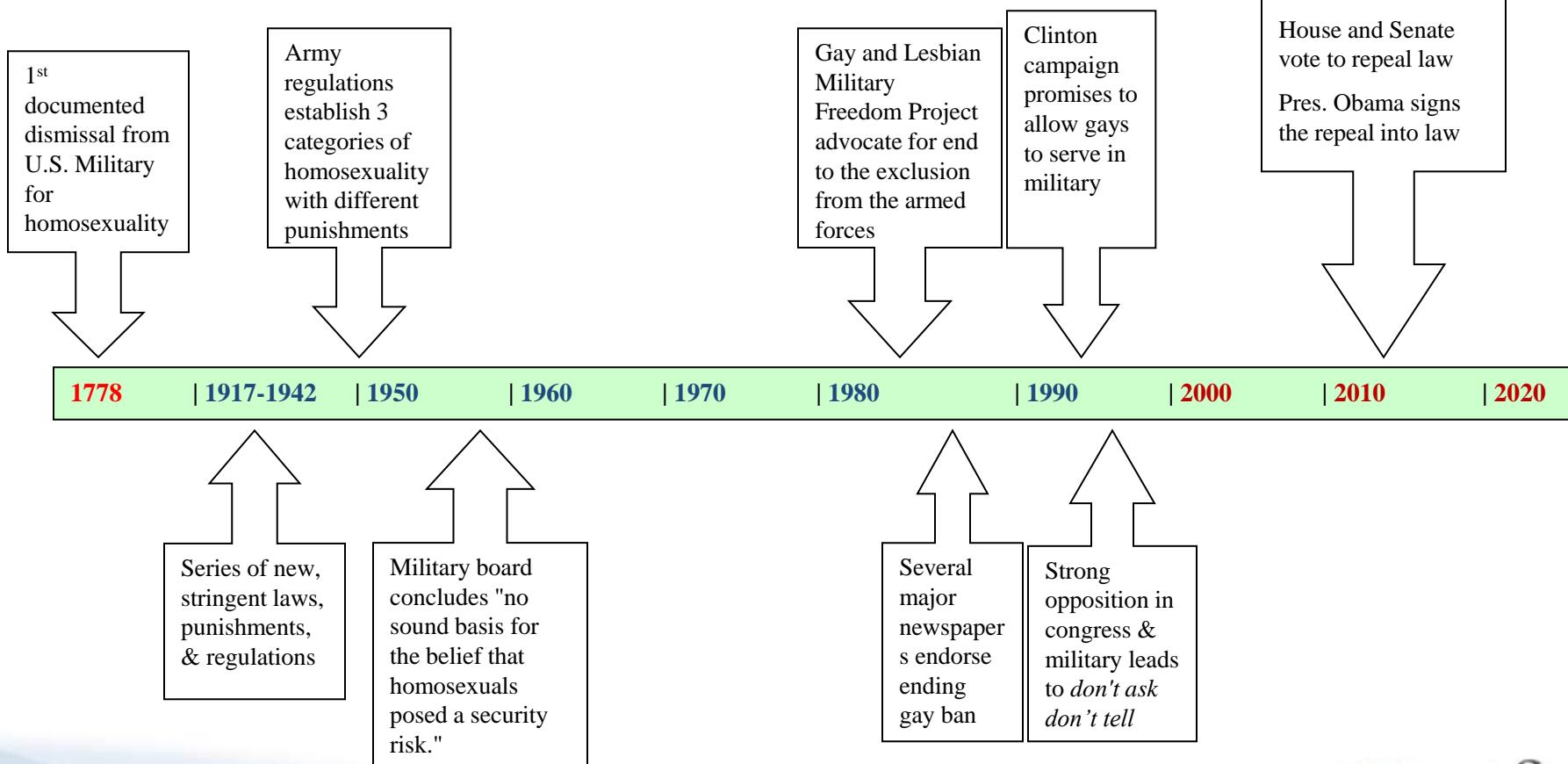
1. Where we are today
2. How we got here
3. Trial disclosure – tip of the iceberg
4. Rethinking how we approach trial disclosure
5. Help is on the way...

Public interest

- Societal interests are typically defended through a developing, but bumpy, set of public policies
- Once opened, the public interest doorway is difficult to close
- A recent example of how things change...

¹Pigou, A. C. (1932) *The Economics of Welfare*. London: Macmillan and Co.

How things change



Public interest in clinical trials

- Historical concerns with which, how, and where clinical trials is made available
- Dramatic shift in the perception of clinical trial transparency²:
 - GSK has announced that it would share detailed data from all global clinical trials conducted since 2000.
 - Andrew Witty, GSK CEO: “really ensure that we were more in step with where I thought, frankly, society and the world was moving.”
 - The European Medicines Agency is considering a policy to make trial data public whenever a drug is approved.
 - Roche’s transparency pledge had arisen from “the call from society in general for greater transparency of the clinical trials that we have.”

²New York Times. June 29, 2013. <http://www.nytimes.com/2013/06/30/business/breaking-the-seal-on-drug-research.html>. Retrieved July 15, 2013.

Roadblocks to full data transparency

- Challenges
 - Personal privacy protection
 - Intellectual property/competitive advantage
 - Logistical issues
 - Effort
 - Technology limitations
- Success stories:
 - Auto industry (CAFE standards)
 - Energy industry

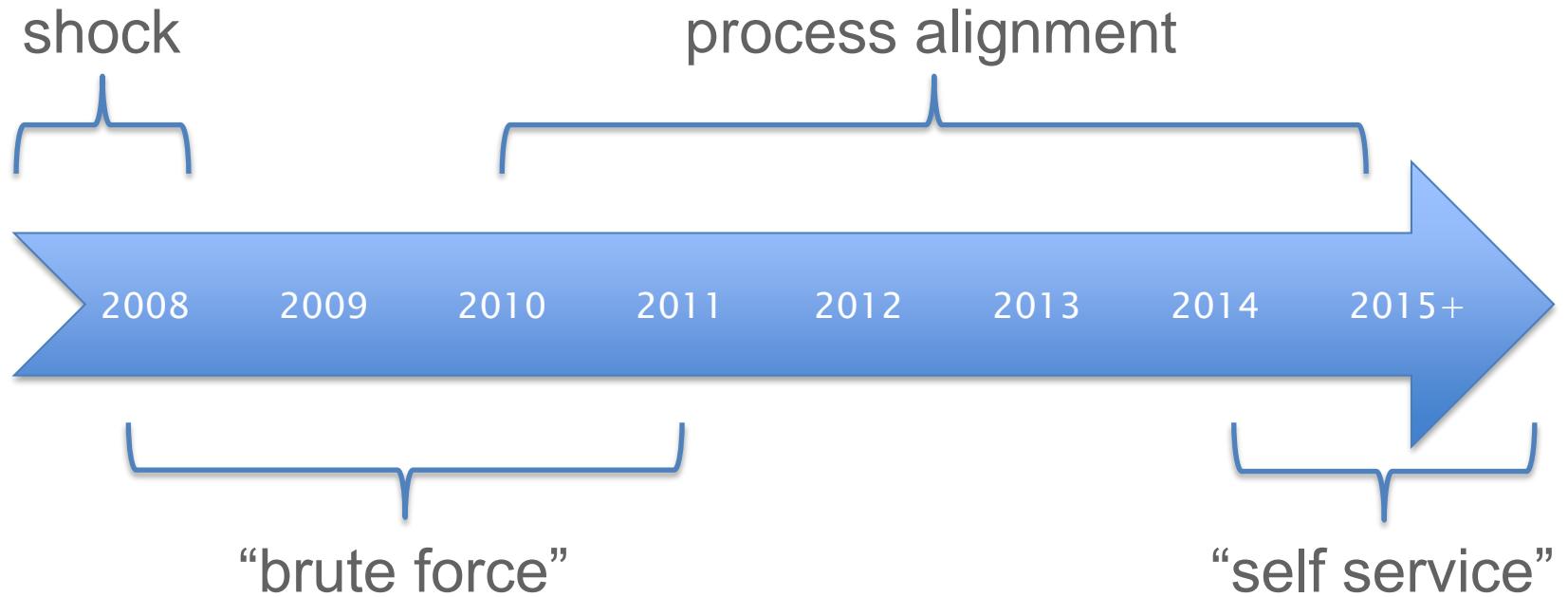
Clinical Trial Transparency – tip of the iceberg

- Increasing volume of data
- Increasing number of requests
- Numerous additional sources of requests
- Growing number of uses of data
- Little process by which data is requested or standards in which data is delivered



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Changing the approach to clinical trial transparency



How your CIO is making your life easier

1. Implementing self-describing data systems

- Providing data tables and datasets which provide their own context and description

2. Implementing information “trackability” everywhere

- Providing context of the data’s source or “pedigree”, including how and where it is being used

3. Implementing “data discovery” platforms

- Integrated portals where data can be extracted without technical knowledge or joined with other data to produce a foundation for new knowledge acquisition



Conclusion

1. “Complete” data disclosure is in the public interest
2. Short term roadblocks in data disclosure will be overcome
3. We are just beginning an era of increased transparency
4. Technology can help, CIOs are actively pursuing solutions which will make data far more accessible both inside and outside the organization
5. Trial disclosure processes, fueled by increased transparency and powered by an era of new technology, will become much easier, if implemented correctly