Advancing the National System through Optimal Balance between Patient Protection and Transparency: The Common Rule and Beyond

Industry Perspective

MDEpiNet Annual Meeting

October 1, 2015

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Thank you for the efforts so far!

Success is about Achieving Balance

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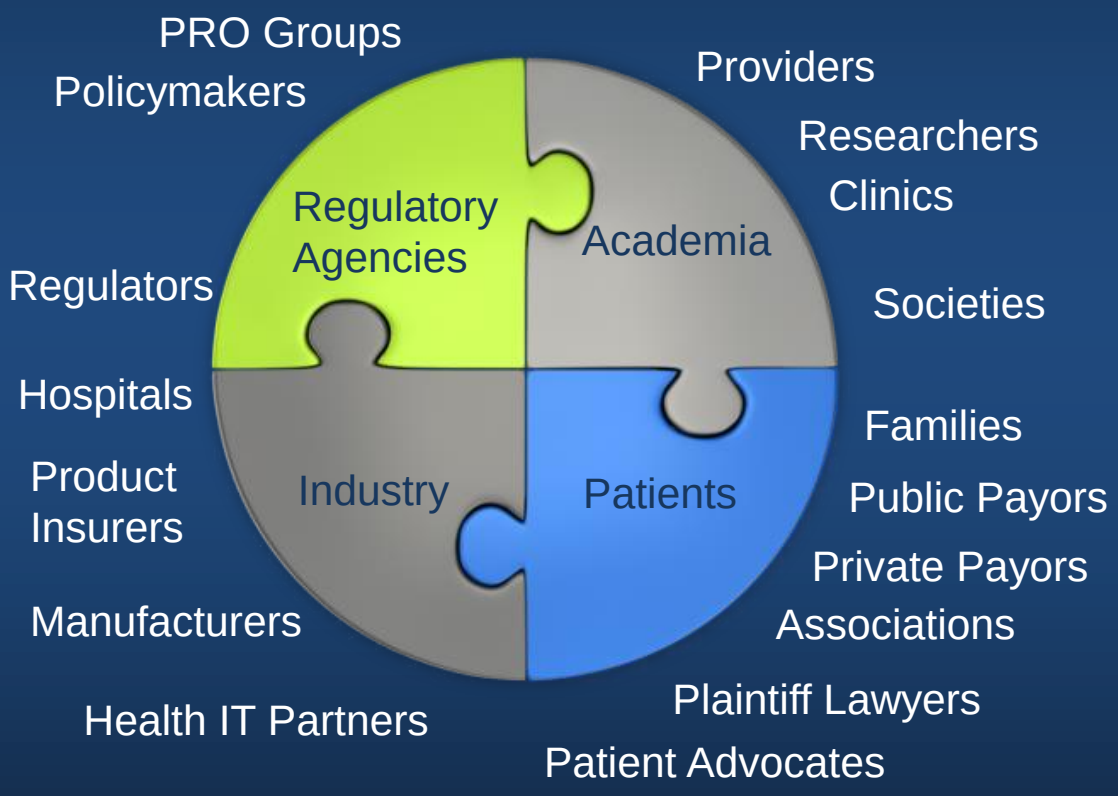
- Stakeholder Engagement
- Informed Consent
- Transparency

Industry Perspective: Work Together to Achieve a Balanced Ecosystem



If all parties are not included in the decision-making process, likely to result in many unintended consequences.

Changes made to the Ecosystem must be holistic

#1 Operability of registries?

What legislative or policy changes are required to operationalize FDA use of registry data without traditional informed consent?

- Can FDA rely on registry data for:
  - Near Label Use for Expanded Indications
  - New Indications
  - Labeling
  - Product Approvals

- Has CDRH resolved barriers to using registry data as a basis for determination?

#2 New common rule – balance perspective

In an attempt to strengthen / shorten the informed consent, whose concerns are not addressed?

Product liability insurers?
Patient advocates?

How can we mitigate the concerns of all stakeholders?
What statutory protections should accompany the new common rule?

Informed Consent

We reviewed an ICF from one of our currently enrolling device studies

	CURRENT ICF	PORTION REQUIRED BY PART 50	PROPOSED CHANGES
Pages	18	11	2-3
Paragraphs	134	82	23
Sentences	275	171	15
Lines	549	338	31
Words	4364	2704	242

Global Impact of Informed Consent

How will the new common rule affect global transportability of data? Global harmonization and acceptance?

Element	ISO 14155	GCP	21 CFR 50	Japan GCP	China GCP	HIPAA	EU Data Auth	Sponsor	Site
Product									
Procedures									
Risks									
Benefits, payments, costs									
Data Protection									
Signature Page									

Changing the Informed Consent

Unintended Consequences:

- Shortening the Informed Consent renders many stakeholders a target for increased allegations of "failing to inform"
- Issues not covered in the Informed Consent become liabilities
- Increasing liability reduce industry-sponsored research and drive studies overseas

Must clarify the legal framework and pass legislation or statutory protection to clearly exempt uncovered issues from legal action

#3 Transparency vs. privacy

As we push for increased transparency, which stakeholders are we pressuring to assume greater risk?

How do we achieve agreement on de-identification processes that protect patient identity, yet make data available via EHRs and linkable across systems?

Actions and Reactions

Transparency Objective	Intended Consequence	Concerned Stakeholders	Potential Unintended Consequence
Open access to research results	Increase transparency, increase public trust, increase participation	Investigators Institutions Industry Societies Insurers	Patient discrimination, exposure, data misinterpretation, risk to intellectual property, authority, privacy
Collect standard care data through EHR for secondary use	More/faster/better postmarket evaluation, increase data collection efficiency, lower administrative costs	Institutions Payors Regulators Patients Advocates	Data quality concerns, analysis methods, 'normal' patient privacy provisions, non-acceptance by global regulators?

Transparency

Transparency and understanding generally improve acceptance, but…

what are the unintended consequences?

- Threat to trade secrets, intellectual property, government internal procedures, patient class discrimination, unwarranted legal claims.

What is the process for addressing each stakeholder concern in a balanced way?

How can we achieve balance?

While these issues remain unresolved, they can be solved through

- Meaningful participation from breadth of stakeholders in the governance, oversight and decision-making processes (policy and planning, data use, analysis).
- Ensuring that unintended consequences are fully explored when developing reforms.
- Addressing the unintended consequences now. Failing to do so will result in increased costs, decreased research funding, and unusable data.

Together…

All issues can be resolved, including all stakeholders

- FDA determinations based on registry data
- Public education, statutory protections, and process for practical informed concern
- Public workshop on IRB reform
- Define public transparency