IOM Sharing Clinical Research Data Workshop

Standardization to Facilitate Data Sharing

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We are operating in a changing health care landscape

Industry's Old World

- Most innovation and development came from a small set of usual suspects
- If you develop it, they will prescribe it
- Payment for volume and unconstrained growth
- Paper-based medical records
- Measurement in clinical trials only
- Focus on physician as trusted intermediary
- Data in hands of few

The New World

- Fast pace of change with wide range of participants—large and small
- Need to demonstrate comparative effectiveness
- Value-based models of payment and focus on sustainability of system
- Expanded use of health information technology in clinical practice
- Continuous measurement of practice
- Increasing focus on the patient
- Movement towards data liberation

Merck Values on Use of Patient Health Information

- Merck's priority is the privacy and security of patient health information

- Merck will work with patients and clinicians to transparently demonstrate the value, safety, and effectiveness of its products through careful, longitudinal analysis of patient information

- Merck will use patient health information to preserve access and promote use of effective medications that improve care of patients

Merck has already assumed leadership in clinical trial transparency

- Effective July 1, 2011 when Merck submits a manuscript on a study of an investigational or an approved medicine or vaccine to a biomedical journal, Merck will include the protocol and statistical analysis plan as part of the submission package.

- Upon a journal's acceptance of the manuscript for publication, Merck will provide the journal with the opportunity to post on its web site, at journal's discretion, the **key sections of the protocol, including the objectives and hypotheses, patient inclusion and exclusion criteria, study design and procedures, efficacy and safety measures, the statistical analysis plan, and any amendments relating to those sections**. Merck proactively communicated this policy to 350 editors of medical journals

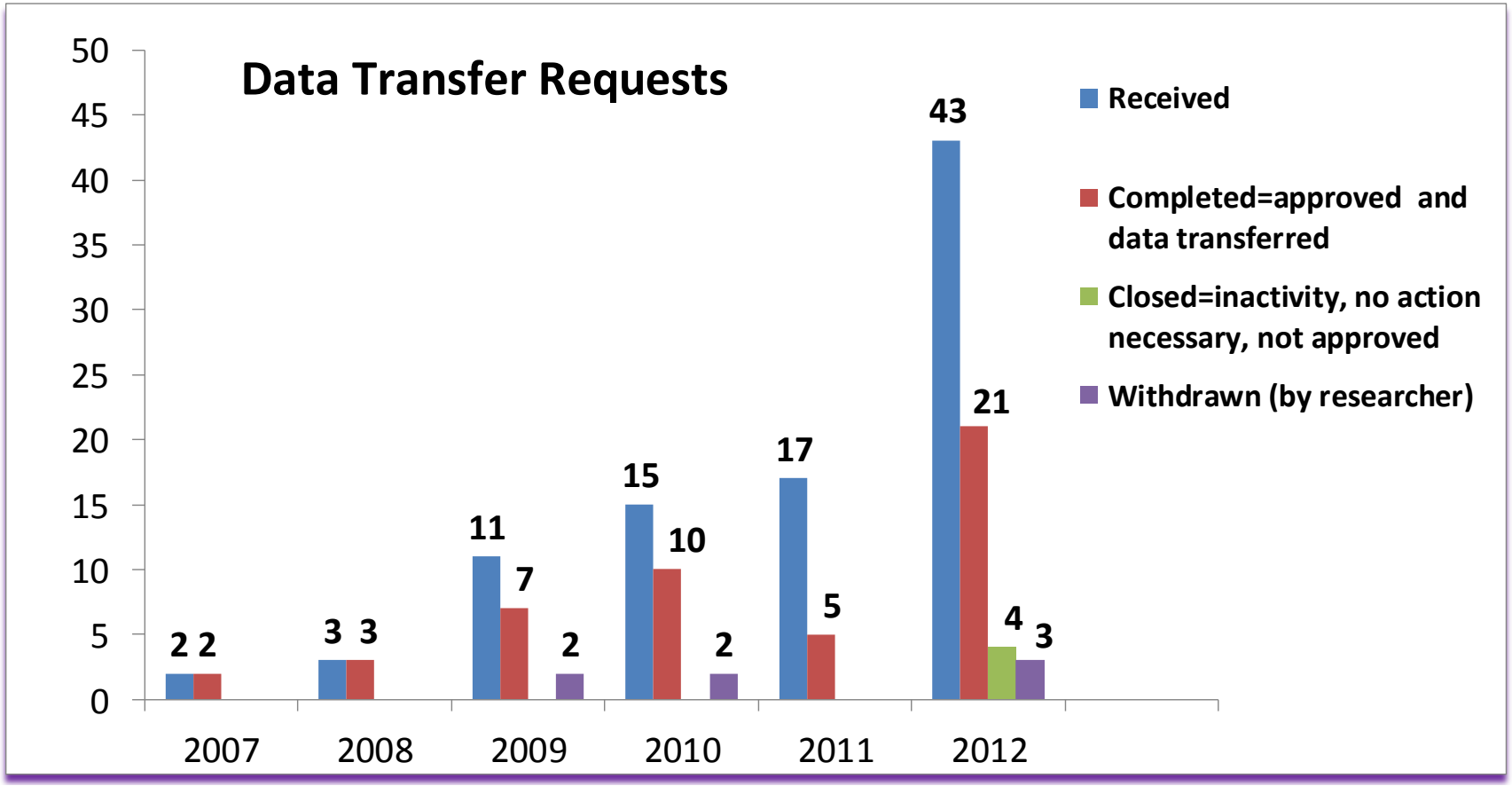
Framing the issue: sharing participant-level data from clinical trials

- Significant amounts of clinical trial data – both within and outside industry - does not get published
- New insights can potentially be gleaned from additional analyses of clinical data
- Concern among scientists and clinicians that selective publication of data fail to tell “the whole story” of a medication
- Concerns and risk aversion within industry that data can be (mis)used to produce analyses that misrepresent a product’s effects and hurt patient access to essential medications
- Need for a thoughtful, equitable approach to sharing data that includes partnership between industry and academia

Merck is in early stages of making more patient-level clinical trial data available

- growing recognition of the clinical value and importance of sharing clinical data
- Strong consideration of both prospective and retrospective approaches to sharing data
- A start-up initiative that allows external investigators to apply access to Merck data for independent studies

Merck's External Data Transfer (EDT) initiative is growing



Early lessons learned and next steps

- Need to overcome the cultural sensitivities around sharing data externally and internal
- Need to create broader recognition of need for and interest in data transfer
- Need to be inside-out and outside-in
- Need to streamline and unify process
- Strong internal willingness to collaborate in academic-industry partnerships to make more data available