Promoting Clinical Trial Data Transparency Conference

March 30-31, 2015, Harvard Faculty Club

Deloitte.

MRCT Data Sharing Conference

Pre-Conference Survey Findings

March 30, 2015

Promoting Clinical Trial Data Transparency: Results of Pre-Conference Survey

The pre-conference survey focused on commonalities, limitations and gaps of current data sharing approaches

Survey Participants

A total of 21 interviews were conducted over two months to identify commonalities, limitations and gaps of current data sharing approaches. Each organization identified one individual to be interviewed for responses.

Common principles were identified for sharing of participant level clinical trial data

Promote sharing of data to advance science and improve public health while

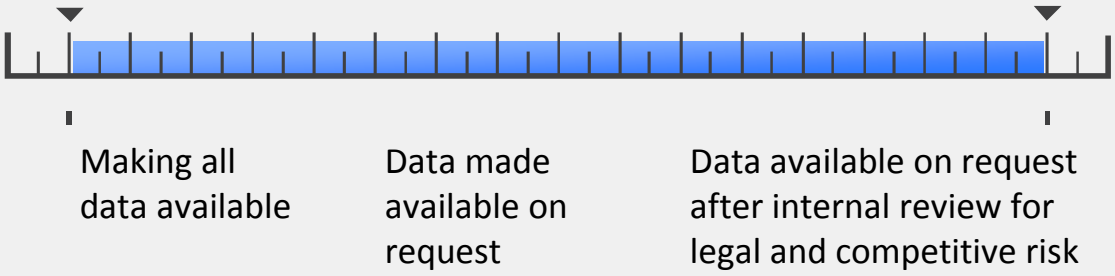
- protecting patient rights and privacy
- ensuring responsible conduct of research and good stewardship of data
- maintaining incentives for those who generate data to conduct new research

The value of data sharing is strongly supported, but specifics of what data to share varies

100%
Of respondents support data sharing and the aggregation of data

Although all survey respondents were supportive of data sharing there were a variety of different opinions around what it means to share participant level data

Spectrum of data sharing



A central system that allows interoperability is widely considered to be the preferred option however many challenges need to be addressed

System Requirements

Common Data Standards

Standard Data Use Agreements

Protected Personal Information

Standard Processes

Cross-Sponsor Solutions

Analytical Tools

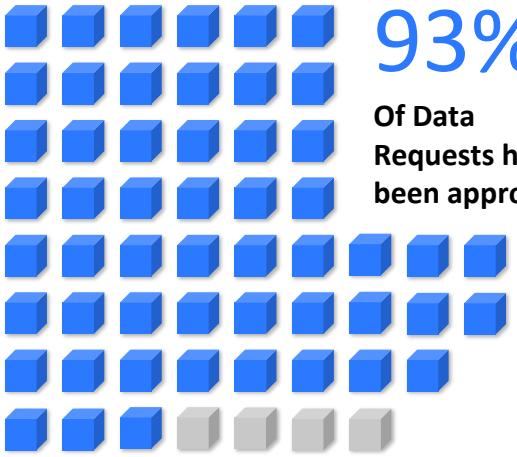
Current System **Gaps**

- Use of a common data standard
- Resources to anonymize data
- Data repository for academics
- User friendly system
- Ability to combine data easily
- Common criteria or common review board

To improve transparency, sponsors plan to or currently publish metrics of requests and track reasons for denials

Source	Number of requests	# in process	# approved	# denied	# incomplete or withdrawn	Monthly Average	Time period
CSDR*	92	38	37	4	13	4.6	5/2013 – 12/2014
Pfizer	15	3	8	0	4	1.25	1/2014 – 12/2014
YODA	9	1	8	0	0	1.8	10/2014 – 2/2015
Total	116	42	53	4	17		

*Note CSDR data is an aggregate of 11 sponsors



93%

Of Data Requests have been approved

Reasons for denying a request for data include:

- Proposal lacks clear scientific merit
- Data requested is not appropriate for the study proposal
- DUA was not signed
- Project aim is commercial or litigious
- Out of scope for what is to be shared per policy
- Out of scope for informed consent
- Studies still in conduct
- Not seeking access to anonymized patient level data

To achieve a shared vision for an interoperable system key process points should be harmonized