Promoting Clinical Trial Data Transparency Conference
March 30-31, 2015, Harvard Faculty Club
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.

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

- **Making all data available**
- **Data made available on request**
- **Data available on request after internal review for legal and competitive risk**
A central system that allows interoperability is widely considered to be the preferred option however many challenges need to be addressed.

**System Requirements**

- Prefer a privately-run central system vs. a federated model

90%

**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

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*Note CSDR data is an aggregate of 11 sponsors

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

93% Of Data Requests have been approved

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